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Electronic Patient-Generated Health Data to Facilitate Prevention and Health Promotion: A Systematic Scoping Review Protocol

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ABSTRACT

Introduction: Rapidly expanding digital innovations transform the perception, reception and provision of health services. Simultaneously, health system challenges underline the need for patient-centered, empowering and citizen-engaging care, that facilitates a focus on prevention and health promotion. Through enhanced patient-engagement, patient-provider interactions and reduced information gaps, electronic Patient-Generated Health Data (PGHD) may facilitate both, patient-centeredness and preventive scare. Despite that, comprehensive knowledge synthesis on their generation, utilization and impact for prevention and health promotion purposes is lacking. This review aims to fill that gap.

Methods and Analysis: This study will be guided by Arksey and O' Malley's methodological framework for scoping reviews, as well as its advanced version by Levac, Colquhoun and O'Brien. The electronic databases Medline, CINAHL, PsycInfo, Scopus, Web of Science, EMBASE and IEEE Digital Library will be systematically searched, using a pre-defined set of search terms. Key electronic journals will be hand searched, while grey literature will be retrieved through searches in grey source databases, various search engines and key webpages. We will additionally screen the reference lists of included documents and consult authors for potentially missed literature. Study selection and data extraction will be conducted by two independent reviewers. We will include literature with a focus on electronic PGHD and linked to prevention and health promotion. Analysis will be narrative and the entire process will be guided by Shapiro et al.'s adapted framework on PGHD flow.

Ethics and Dissemination: This scoping review aims establish a baseline understanding of electronic PGHD generation, share and utilization for preventive purposes. The chosen methodology is based upon the use of publicly available information and does not require ethical approval. Review findings will be disseminated in digital health conferences and symposia. Results will be published and additionally shared with relevant local and national authorities.

Keywords: digital health, e-health, patient-generated health data, user-generated health data, prevention, health promotion, health technologies

STRENGHTS AND LIMITATIONS OF THIS STUDY

- The results of this review will establish a comprehensive conceptual understanding of electronic patient-generated health data (PGHD) utilization for prevention and health promotion purposes; currently lacking in existing reviews
- The addressed topic on PGHD utilization is highly relevant to currently emerging healthcare challenges and in line with increasing advocacy for patient-centered approaches
- The methodology described in this protocol is rigorous and transparent, following established guidelines for scoping and systematic reviews
- As this review's focus lies in disease prevention and health promotion, the resulting typology of electronic PGHD is restricted to those used for such purposes and might thus not be fully transferable beyond that research area
- Despite establishing a conceptual understanding, the study will not formally assess the quality of included literature

BACKGROUND

Emerging and continuously reinvented digital innovations, such as wireless mobile devices, wearables, interactive online platforms and electronic data collection tools exert a transformative power on many domains of human action and interaction.[1, 2] With accelerating public interest in utilizing electronic tools for monitoring, managing and maintaining health and well-being, the healthcare market becomes an increasingly important field of current digital developments.[2] The literature often refers to a "revolutionary enabling" potential of digital innovations in facilitating the provision of care, carrying implications for patients, healthcare providers and policy makers.[3, 4]

Rapidly expanding digital ecosystems, such as the Internet of Things, broadly defined as the process of connecting and using various daily life objects via the internet, are defined as highly disruptive and key for improving healthcare, while reducing associated costs.[5-7] Technological advances can facilitate the creation of valuable health information, as well as its effective use for enabling informed decision making and better outcomes.[4] Simultaneously, the penetration of interactive, dynamic and connected digital tools in daily living ultimately expands the roles of consumers, patients and care providers.[8] Individuals can quantify and track their health by digitally capturing vital parameters and behavioral data, while healthcare providers can potentially use new technologies and generated information to move beyond predominantly curative responsibilities and engage in pro-active, predictive and preventive action.[8]

Parallel and closely related to those new possibilities of self-tracking and capturing owns own health parameters is the emerging movement of patient-, or people-centered healthcare.[9,10] Traditionally, political decision makers and healthcare providers played a predominant role in shaping healthcare organization, management and provision.[9, 11] Modern healthcare systems could benefit from higher patient engagement, stronger communication channels, efficient information

flows and improved adoption of communication and information technologies.[12, 13] Aiming to respond to those needs the Institute of Medicine emphasizes the importance of patient-centered care, defined as the provision of health services that are sensitively build around the needs and preferences of those who receive them.[14] The World Health Organizations (WHO) global strategy on people-centered care and integrated health services underlines that a failure to shift towards predominantly consumer-focused practice will inevitably cause fragmentation, inefficiencies and long-term unsustainability.[9] A conceptual model, developed by Sholl et al. in 2014, highlights the importance of information exchange, active patient involvement and patient-empowerment.[15] Knowledge transfer, flow and accessibility of health data, as well as the availability of adequate technology are additional facilitators of patient-centered health services.[10] Finally, evidence suggests that patient-centeredness is associated with higher patient satisfaction and well-being, which in turn can act as mediating factors towards increased patient-engagement, health consciousness and improved health behavior.[16]

The phenomenon of electronic patient-generated health data (PGHD) can be positioned on the intersection between the digital revolution and the patient-centered care movement. A landmark whitepaper, prepared in the US Office of the National Coordinator for Health Information Technology, defines PGHD as "*health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information—created, recorded, gathered, or inferred by or from patients or their designees (i.e., care partners or those who assist them) to help address a health concern*".[17] Electronically captured, shared and utilized PGHD consists of digitally rooted information, created outside traditional healthcare contexts.[17] For example, diabetic patients can self-measure their blood glucose levels at home and easily upload the results on interactive, provider-connected online platforms, enabling professional feedback, as well as encourage patient engagement and behavioral adaptation, action or change.[18] Similarly, cardiovascular disease patients can self-capture vital signs, such as blood pressure, and rapidly transmit them via online-

connected mobile phones, triggering specialist feedback whenever the recorded values deviate from pre-defined standards.[19] While these are only two examples, they underline the potential of digital health and PGHD as a resource in enabling convenient, patient-centered and cost-effective care, that is simultaneously pro-active, informed and prevention-focused.[20, 21]

STUDY RATIONALE

With increasing prevalence of chronic conditions, proactive and preventive action becomes increasingly vital for decision makers, providers, as well as patients.[22] If implemented effectively, preventive care holds benefits for individuals, healthcare systems, businesses and society as such, reducing the risk of disease, discomfort and disability, diminishing avoidable expenditure, promoting a productive workforce, as well as fostering healthy communities.[22] Achieving successful prevention ultimately requires a patient-centered approach, that facilitates patient engagement and empowerment, as well as meaningful patient-provider interactions.[22, 23]

Without disregarding significant PGHD-related challenges, commonly of financial, technical, practical and ethical nature, evidence suggests that digitally enabled PGHD utilization can facilitate both, prevention and patient engagement, ultimately reducing unnecessary costs and inefficiencies.[12, 13, 17, 24-26] Furthermore, PGHD can add comprehensiveness to the assessment of an individual's health status by reducing information gaps, enhance patient-provider interaction and reduce data errors.[25-27] Research also indicates improved health literacy of patients and consumers, enhancing their knowledge on given conditions and health risks.[24]

Despite the benefits associated with the capture and use of electronic PGHD, systematically and comprehensively synthesized knowledge on their utilization for preventive and health promotion purposes appears to be lacking. Similarly, existing

research appears to be thematically fragmented, as most primary studies and reviews predominantly focus on specific types of PGHD at a time. For example, two scoping reviews, by Archer et al. and Davis et al. address PGHD in relation to personal health records and without a primary focus on prevention and health promotion.[28, 29] Other studies, such as the ongoing Cochrane review by Ammenwerth et al., capture PGHD as an additional functionality of electronic health records, retaining a predominant focus on patient access to provider-generated health information.[30] Acknowledging that PGHD are not merely restricted to personal or electronic health records, this review is built on the rationale that a systematically applied broad focus will ultimately enable a holistic and conceptually enriching understanding of their utilization and preventive potential.[31]

STUDY OBJECTIVES

The overarching objective of this study is to identify, map and synthesize existing knowledge on the generation, share, utilization, context and impact of electronic PGHD for the facilitation and provision of preventive care, as well as health promotion. In order to achieve that, we have defined six targeted objectives, classified into three thematically linked components, aimed at guiding data extraction and synthesis. Table 1 provides a detailed account of this review's objectives.

Table 1 Scoping Review Objectives

Overarching Objective: Identify, map and synthesize existing knowledge on the generation, share, utilization, context and impact of electronic patient generated health data (PGHD) for the facilitation and/or provision of preventive activities and health promotion

First Targeted Objective: Provide an Overview of PGHD Types and Tools

- Identify and map existing types, as well tools of electronic PGHD. The term "types" encompasses data properties and characteristics, as well as their preventive and health promoting aims and functions. The term "tools" denotes captures the utilized technical infrastructure for PGHD creation and utilization.

Second Targeted Objective: Explore the Roles of Patients/Consumers, Providers and their Interaction

- **Patient/Consumer Roles:** Identify and synthesize existing data on the patient/consumer activities and literacy, related to electronic PGHD generation, transfer and utilization for preventive activities and health promotion, as well as associated barriers and facilitators within their context

- **Provider Roles:** Identify and synthesize existing data on the actual or potential utilization of electronic PGHD for prevention and health promotion, placing emphasis on provider activities and literacy, the integration of such data, as well as associated barriers and facilitators within the respective context

- **Patient/Consumer-Provider Interaction:** Identify and synthesize existing data that links the utilization of electronic PGHD to patient-provider interaction, in the context of preventive activities and health promotion

Third Targeted Objective: Explore the Implications of PGHD on Health Outcomes and Equity Considerations

- **Health Outcomes:** If available, synthesize existing data on the impacts of PGHD on prevention and health promotion related outcomes

- **Equity Considerations**: Identify whether and what proportion of identified literature addresses, explores or mentions actual or potential PGHD implications on

health inequities, for example by addressing the digital divide, socio-demographic characteristics or disadvantaged population groups

The first targeted objective ultimately aims to enable an improved, comprehensive understanding of PGHD, while unifying a currently fragmented literature-base into a structured, practical typology. The second targeted objective aims to facilitate a conceptual understanding of how such data are utilized to offer preventive activities and health promotion, emphasizing on patient activities, provider roles and patient-provider interactions. Current gaps in synthesized knowledge related to the utilization and impact of PGHD for prevention and health promotion purposes underline the importance of those elements. Closely related to that, the last objective aims to synthesize findings on potential impacts and implications of PGHD-utilization on prevention and health promotion related outcomes, as well considerations regarding health equity. Acknowledging that differences in technological access, use and literacy may replicate social inequities in the digital domain, we consider it essential to capture any indication related to potential or actual equity implications of electronic PGHD.[32] Finally, inherent to our overall aim of mapping and synthesizing existing knowledge, we expect to draw final conclusions on current research trends and apparent gaps.

METHODS AND ANALYSIS

Conceptual Model and Definitions

In order to guide and structure the scoping review process, we have adapted and utilized a conceptual framework, prepared for the US office of the National Coordinator for Health Information Technology and reported in a 2012 White Paper.[17] The original framework visualizes the flow and context of PGHD, emphasizing on data capture, transfer and review.[17] Our adapted version,

provided in figure 1, retains the same flow, however, additionally emphasizes the use of PGHD for fostering or providing disease prevention, health promotion and patient-provider interactions. The framework visualizes the generation of different health data types by patients, their transfer and integration within the healthcare context and their use for preventive care and patient-provider communication. The grey line in the middle indicates that provider involvement might not always be direct, with patients remaining primarily responsible for the use of such information to prevent disease and promote health.

Figure has been uploaded separately and should be added here

Figure 1: Adapted Framework for PGHD Flow and Context for Prevention and Health Promotion.[17]

In addition to the definition given in the background section of this report, we define PGHD as created outside regular healthcare settings, while being distinct from other forms of patient-provided data, such as patient-reported outcomes (PROs).[17, 33] PROs are commonly informed, standardized and driven by healthcare providers, lacking the level of patient control that is characteristic for PGHD.[17, 33] Furthermore, this review will be exclusively focusing on electronic PGHD, generated or transferred through any type of digital tools.

Health promotion is defined by the World Health Organization (WHO) as any activity that aims to empower people in achieving control over and enhance their health.[34] Prevention is defined as any activity that intentionally aims to impede, reduce or delay the occurrence or progress of physical or mental ill health, injury and premature death.[35] We will not differentiate between primary and secondary prevention, acknowledging that the boundaries are neither strictly defined, nor clear; especially when it comes to complex chronic conditions.[36] However, preventive measures categorized as "tertiary", driven by an already existing severe

discomfort or disability, go beyond this reviews scope.[36] The reason for that is justified on conceptual and practical arguments. Conceptually, we follow Gordon's classification, that restricts the term prevention to primary and secondary, arguing that tertiary prevention is driven by the manifestation of disease and is thus driven by different dynamics, while often being non-distinguishable from therapeutic activities.[36] Practically, not being able to keep preventive and therapeutic interventions apart, would broaden up our review's scope enormously and lead to an unmanageable amount of literature.

The term 'healthcare context' denotes the involvement of healthcare providers in PGHD-facilitated preventive care and health promotion. The term provider is defined as any professional that is responsible for offering health-related services (e.g. primary care physicians, primary care nurses, pharmacists, specialist physicians, physiotherapists, psychologists). This broad definition aims to maintain a relatively broad scope and reduce the likelihood of missing potential valuable literature. The review will also incorporate studies in which healthcare providers hold secondary roles, such as merely monitoring electronic PGHD, or providing input on the development of preventive digital PGHD-based tools, without directly interacting with patients. Even though the patient-provider interaction and provider involvement might be weak in such scenarios, that literature is crucial to fully understand the different approaches of using electronic PGHD for preventing disease and promoting health. Studies taking place within inpatient & hospital contexts will fall out of the review's scope, considering that disease prevention and health promotion is not a priority activity in such settings. For coherence purposes, the word 'patient' is used interchangeably for healthcare consumer, without necessarily denoting the presence of a disease.

Protocol Structure

This protocol is structured and guided by Arksey and O'Malley's methodological framework for scoping studies, as well as Levac, Colquhoun and O'Brien's work on advancing that methodology.[37, 38] The following six sections are categorized

according to the elements of that framework. Those include identifying the research question (Step 1), identifying relevant studies (Step 2), study selection (Step 3), charting the data (Step 4), collating, summarizing and reporting the results (Step 5) and stakeholder consultations (Step 6).[37, 38] Furthermore, this protocol follows the reporting guidelines of the PRISMA-P checklist for systematic review protocols.[39] Falling beyond the scope of a scoping review, the three PRISMA-P elements let aside are the risk of bias assessment, meta-biases and evidence strength (GRADE).[39]

Step 1: Identifying Research Question

Arksey and O'Malley describe the definition of an appropriate research question as a crucial initial step, that defines and refines the chosen research strategy.[37] The guiding questions of this review have been developed through an iterative process of exchange, consultation and literature acquaintance. After having defined a set of core and sub-questions, experts have been consulted to provide further input and feedback. In line with our intention to comprehensively map and synthesize a potentially fast and fragmented volume of literature on electronic PGHD, the primary, overarching research question of this review is defined as: "*What is our knowledge status, retrieved from existing literature, on the generation, share, utilization, context and impact of electronic PGHD for the facilitation of patient/consumer-centered preventive activities and health promotion?*".

Step 2: Identifying relevant studies

The identification of relevant literature will consist of several combined approaches, including electronic database searches and complementary activities, such as hand searches of selected online journals, relevant webpages, grey literature sources, reference list screening and expert consultations. Initially, we will systematically search 7 electronic databases, including Medline, CINAHL, PsycInfo, Scopus, Web of Science, EMBASE and IEEE Digital Library. Preliminary literature searches,

consultation of thematically related reviews, input from the research team and the support of a specialized librarian led to pre-defined, preliminary search strategy, created on EMBASE and provided in supplementary file 1. Our strategy is purposively sensitive, entailing a variety of keywords related to PGHD, restricted to adult populations and research published in the last 15 years. The final strategy will be refined in consultation with the experienced librarian, which will run all searches. Retrieved documents will be imported in the electronic citation manager Mendeley.

In order to acquire the level comprehensiveness required for a scoping review, we will also hand search key electronic journals, including JAMIA, JIMR, the International Journal of Digital Healthcare, Digital Health (SAGE) and the Journal of m-Health.[37] Grey literature, such as reports, policy briefs, conference abstracts and theses will be retrieved through rigorous searches of the following sources: Grey Literature Report, Open Grey, Web of Science Conference Proceedings and Proquest Dissertations. Ensuring that no relevant publication is missed, we will run several web engine searches, using Google, Google Scholar and Yahoo, screening the first ten result pages. Furthermore, we will screen thematically relevant webpages, such as the Office of the National Coordinator for Health Information Technology (ONC), the Healthcare Information and Management Systems Society (HIMSS), the Patient-Centered Outcomes Research Institute, the Research Triangle Institute International, the Agency for Healthcare Research and Quality (AHRQ) and Digital Health Canada, for additional outputs. Manual reference list screening of all eligible studies, as well as author consultations, requesting input on potentially missed or unpublished work, constitutes the last step of our research strategy.

Step 3: Study Selection

The study selection process will consist of two phases, independently conducted by two members of the research team. The first phase includes the title and abstract screening of all identified documents. The second phase consists of full-text review

of studies that will be classified as potentially eligible during phase one. During both phases, reviewers will assess study inclusion against a set of pre-defined eligibility criteria, listed in table 2. Final eligibility requires a clear focus on electronic PGHD, linked to disease prevention and health promotion, even as a minor topic, as well as some reference to patient roles or healthcare provider involvement. The absence of elements or indicators referring to prevention and health promotion (e.g. reduction of blood pressure) or a shallow exploration of patient or provider attitudes towards PGHD and PGHD-based tools, without addressing any prevention or health promotion-related outcomes, will lead to exclusion. To ensure that the chosen eligibility criteria are sensitive and clear enough to capture relevant documents, they will be pre-tested by both reviewers on a sample of studies that have been identified during preliminary searches. Maintaining a broad scope, this review will consider any type of primary research study designs, as well as grey literature. Relevant systematic reviews will be considered as sources of potentially valuable primary research.

We will assess inter-rater agreement during both phases, using Cohen's k coefficient.[40] To ensure that the eligibility criteria are valid and applied correctly by both reviewers, the screening of the first 50 titles and abstracts will be followed by consultation and comparison. Strong deviances will result in criteria adjustments and repetition of the process for the next 50 titles and abstracts, until uncertainties are minimized. Any paper that at least one of the reviewers deems as potentially eligible will be considered for full-text review. After selecting all potentially eligible documents, the reviewers will independently complete the full-text screening phase and meet to compare their results. Disagreements will be followed by repeated full-text review of all discordant articles, as well as discussion with a third reviewer. To ensure highest levels of process transparency and reproducibility, the entire process will be captured and visualized in a PRISMA flow chart, including the most common exclusion reasons, as well as the final number of included documents.[41]

Table 2 provides the selected eligibility criteria, carefully chosen to guide the identification of eligible studies, while counterbalancing the relatively high sensitivity, inherent to the review's broad research question. Documents will be eligible only if fulfilling all four criteria.

Table 2 Eligibility Criteria

Inclusion	Exclusion
1. Addresses the generation, share, utilization or impact of electronic patient-generated health data (PGHD) in any of its forms and in accordance to the definition provided in this report	1. Does not address generation, share, utilization or impact of electronic PGHD
2. Describes, explores or analyses some form of utilization of electronic PGHD for prevention and health promotion purposes, in line with the definitions provided in this report	2. Missing prevention and health promotion aspect (e.g. exclusively addressing rehabilitation or therapeutic interventions)
3. Describes, explores or analyses patient/consumer involvement or activities related to the creation, share and utilization electronic PGHD	3. Addresses patient-generated information that is not personal health-related (e.g. patient/consumer opinions) or does not describe, explore or analyse any patient/consumer involvement or activities
4. Describes, explores or analyses some form of healthcare provider involvement (direct & indirect) on the utilization of electronic PGHD	4. Does not describe, explore and analyse some form of direct or indirect healthcare provider involvement
5. Written in English or German	5. Written in a language other than English or German

Step 4: Charting the data

Data extraction will be conducted independently by two reviewers, guided by a pre-defined, however flexible data extraction form. The preliminary form, as developed by the research team is provided in table 3. It aims to ensure that all required information is captured practically, efficiently and accurately, minimizing the risk of missing information. Arksey and O'Malley's methodological framework suggests charting the data according to central research themes.[37] Thus, the chosen data-extraction elements have been developed in line with the reviews objectives and corresponding research questions. Next to general information, we aim to retrieve data on patient activities, PGHD types, provider responsibilities for PGHD utilization, as well as impacts on disease prevention and health promotion.

The final form will be refined and validated through consultations with the entire research team, as well as expert feedback. As suggested by Levac et al. and Daudt et al., the form will be initially independently tested by two reviewers on a random sample of five studies.[38, 42] Daudt et al. describe that phase as key to improving the quality and applicability of the data extraction chart.[42] That step will be followed by consultation to ensure accuracy, consistency and that the captured information contributes to the study's research questions. Consultation might finally lead to form modifications, reviewed and agreed upon by the entire research team.

After completion of the full data extraction process, both reviewer's final data-sets will be compared. Each article will be attached to a unique identification number to enhance process efficiency and practicality. Inconsistencies and disagreements will be discussed, re-consulting the respective documents and if necessary, requesting support by a senior investigator of the team.

Table 3 Preliminary Data Charting Elements

Element & Sub-element	Associated Question
Publication Details	
Author & Affiliation	Who wrote the study/document?
Type	Is the document an empirical study or grey literature?
Year	What year was the study/document published?
Country/Region	Which country is the study/document focusing on?
Funding	Are the funding sources provided?
Conflict of Interest Declaration	Is a conflict of interest statement included?
General Details	
Methodological Design	What is the study/document design?
Aims	What are the study/document aims?
Population	What the target population of the study/document?
Addressed condition(s), risk factors(s), symptom(s), behavior(s) or outcome measure(s)	What is the health-related focus of the study/document?
Setting	What is the described setting?
Perspective (Promotion/Prevention)	Is the focus on prevention or health promotion?
Content	
Patient Roles and Activities ➢ PGHD generation ➢ PGHD transfer & use ➢ Context ➢ Barriers & Facilitators	What are the patient roles and required activities in generating, transferring and using electronic patient-generated health data (PGHD) for prevention/health promotion purposes?
PGHD Types ➢ Architecture ➢ Aims and Purposes	What types of PGHD are addressed? What PGHD-based tools are used?
Provider Roles and Activities ➢ PGHD Integration ➢ PGHD use ➢ Context ➢ Barriers & Facilitators	What are the provider roles and required activities in integrating and using electronic PGHD for prevention/health promotion purposes?

Patient-Provider Interaction ➢ Barriers & Facilitators	How do electronic PGHD affect or relate to patient-provider interaction?
Impact on Prevention and Health Promotion-Related Outcomes	What is the impact of electronic PGHD use on outcomes related to prevention and health promotion?
Equity Considerations	Does the study/document address, explore or refer to actual or potential equity-related implications of PGHD? (e.g. better results for disadvantaged social groups)
Other Important Results	Further important results?

Step 5: Collating, summarizing and reporting the results

As described by Arksey and O'Malley, a weighted data synthesis and aggregation of findings is not inherently essential to a scoping review, considering the missing assessment of evidence quality and robustness.[37] The chosen analytical approach will therefore be of narrative nature, guided by the adapted PGHD-flow framework (figure 1) and the review's objectives.[17] Despite its benefits, a quality assessment will not be performed since it does not align with our aim of scoping a potentially large and heterogeneous literature volume.

Initial synthesis will be of basic quantitative nature, summarizing the extent, scope and nature of existing literature. Publication types, years, geographic distribution, target populations, target conditions, risks and behaviors, as well as existing methodologies will be synthesized descriptively and presented in tables. That step will provide an overview of existing evidence and research activity trends, as well as highlight potential research gaps.[37]

Further synthesis will remain narrative but will also consider quantitative primary data. Key findings will be summarized in tables and figures, structured around the review's objectives. The entire research team and experts will enrich data synthesis through regular input, ensuring validity and transparency. With exception of the risk of bias and evidence strength (GRADE) assessment, the reporting of our results will be guided by the PRISMA reporting guidelines.[43] The entire process, including screening (Step 3), data extraction (Step 4) and synthesis will be conducted with the EPPI-Reviewer 4 Software.

Step 6: Consultation

Levac et al., underline that consultation, the sixth, transversal optional stage of the scoping studies framework, may enable stakeholder engagement and provide valuable input, beyond the information provided in the literature.[38] As already described throughout the protocol, expert consultation is central at all stages of this study. We will additionally establish regular consultation with one healthcare provider partner and one consumer partner. Both stakeholders will be asked to provide feedback during data extraction, data synthesis and interpretation. Finally, we aim to engage digital health experts within the team's own institution, receiving additional feedback. All involved experts and stakeholders will be acknowledged in the final publication.

ETHICS AND DISSEMINATION

This review constitutes the first step of a larger research project on digitalized solutions for disease prevention and health promotion and thus, ultimately fulfils the function of establishing a baseline comprehensive conceptual knowledge. Building upon a better understanding on the utilization of PGHD for preventive purposes, the results of this study will be used to inform and back-up prospective research steps. Initiation of data collection is planned for February 2018. Findings will be disseminated beyond internal institutional boundaries, such as during relevant conferences, symposia and related local and national organizations. Results will be published and additionally be shared with our provider and patient-partners and their networks. As our methodology is based on the review of public and existing information, ethical approval is not required.

Authors' contributions: Vasileios Nittas contributed to the conceptualization of the study, wrote and edited the manuscript. Margot Mütsch contributed to the conceptualization of the study, supervised the entire process and edited the manuscript. Milo Puhan contributed to the conceptualization of the

study, supervised the entire process and edited the manuscript. Frederic Ehrler provided regular input and edited the manuscript. All authors provided final approval of the final protocol version.

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Figure Legends

Figure 1: Adapted Framework for Patient-Generated Health Data (PGHD) Flow and Context for Prevention and Health Promotion.[17]. The Framework visualizes the flow of PGHD from the patient/consumer (generation stage), into the healthcare context and provider systems (data transfer and integration) and back to the patient in form of prevention, health promotion and patient-provider interaction.

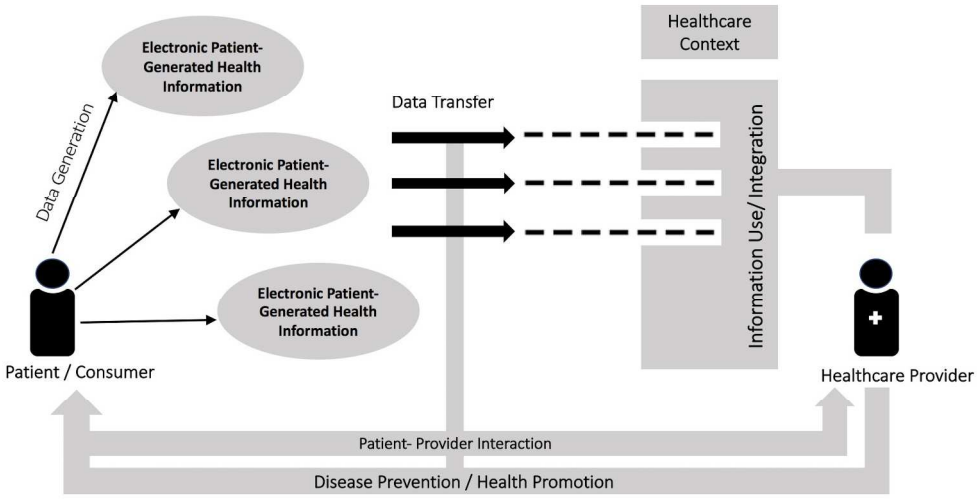

Figure 1: Adapted Framework for Patient-Generated Health Data (PGHD) Flow and Context for Prevention and Health Promotion.[17]. The Framework visualizes the flow of PGHD from the patient/consumer (generation stage), into the healthcare context and provider systems (data transfer and integration) and back to the patient in form of prevention, health promotion and patient-provider interaction.

328x166mm (300 x 300 DPI)

Supplementary File 1: Preliminary Search Strategy, piloted on EMBASE

#1	((patient NEXT/1 (reported OR shared) NEAR/3 (data OR information)):ti,ab) OR (((consumer OR people OR user OR person*) NEXT/1 reported NEAR/6 (health OR medical OR clinical) NEXT/1 (information OR data)):ti,ab) OR ((connected NEXT/1 (health OR medicine)):ti,ab)
#2	((patient NEXT/3 portal):ti,ab) OR (((electronic OR digital OR online OR web* OR internet) NEXT/3 'health diary'):ti,ab)
#3	'electronic patient record'/exp OR 'electronic medical record'/exp OR 'electronic health record'/de OR 'telemedicine'/exp OR (((personal OR user OR consumer OR electronic OR online OR digital OR web OR internet OR computer) NEAR/1 (medical OR health OR clinical) NEXT/1 record):ti,ab) OR ((patient* NEXT/3 record):ti,ab
#4	((patient OR consumer OR people OR user OR person* OR self*) NEXT/1 (generated OR reported OR shared)):ti,ab
#5	self:ti,ab OR oneself:ti,ab OR himself:ti,ab OR herself:ti,ab OR personal*:ti OR connected:ti,ab OR ((personal* NEXT/3 (health* OR medicine* OR care OR manag* OR monitor*)):ti,ab)
#6	#4 OR #5
#7	#3 AND #6
#8	#1 OE #2 OR #7
#9	promot*:ti OR prevent*:ti OR improve*:ti OR (((health OR patient) NEAR/3 (educat* OR communicat* OR advocacy OR literacy OR behaviour OR behavior OR status)):ti) OR (((disease OR health OR personalized) NEXT/3 manag*):ti) OR ((self NEXT/1 (manag* OR monitor*)):ti)
#10	#8 AND #9
#11	'health promotion'/exp OR 'health literacy'/exp OR 'health education'/exp OR 'disease management'/exp OR 'health behavior'/exp OR 'health status'/exp OR ((health NEAR/1 (promot* OR prevent* OR educat* OR communicat* OR advocacy OR literacy OR behaviour OR status)):ti,ab) OR ((disease NEAR/1 manag*):ti,ab) OR (((disease OR medicine) NEAR/3 prevent*):ti,ab) OR ((self NEXT/1 (manag* OR monitor*)):ab)
#12	'devices'/exp OR 'internet'/exp OR 'information processing'/exp OR (((electronic* OR mobile OR smart) NEXT/3 (tool* OR watch* OR device* OR gadget* OR bracelet* OR pager* OR monitor*)):ti,ab) OR (((mobile OR cell OR smart) NEXT/3 phone):ti,ab) OR tablet*:ti,ab OR iphone*:ti,ab OR ipad*:ti,ab OR smartphone*:ti,ab OR wearable*:ti,ab OR app:ti,ab OR apps:ti,ab OR application*:ti,ab OR ((technol* NEAR/3 (consumer OR patient OR user)):ti,ab)
#13	innovat*:ti,ab
#14	#12 OR #13
#15	#8 AND #11 AND #14
#16	#8 AND #11 AND #12
#17	#10 OR #15
#18	((patient NEXT/1 generated NEAR/3 (data OR information)):ti,ab) OR

	(((consumer OR people OR user OR person*) NEXT/1 generated NEAR/6 (health OR medical OR clinical) NEXT/1 (information OR data)):ti,ab) OR ((connected NEXT/1 (health OR medicine)):ti,ab)
#19	(connected NEXT/1 (health* OR medicine OR treat* OR monitor* OR care*)):ti,ab
#20	#17 OR #18 OR #19
#21	'electronic patient record'/exp OR 'electronic medical record'/exp OR 'electronic health record'/de OR 'telehealth'/exp OR 'medical informatics'/exp OR (((personal OR user OR consumer OR electronic OR online OR digital OR web OR internet OR computer) NEAR/1 (medical OR health OR clinical) NEXT/1 record):ti,ab) OR ((patient* NEXT/3 record):ti,ab) OR (((electronic OR digital OR mobile OR tele) NEXT/1 (health OR care OR monitoring)):ti,ab) OR 'e health':ti,ab OR 'm health':ti,ab OR 'e care':ti,ab OR 'm care':ti,ab OR 'e monitoring':ti,ab OR 'm monitoring':ti,ab OR 'internet of things':ti,ab OR telemedicine:ti,ab OR ((health NEXT/1 (it OR 'information technology')):ti,ab)
#22	#6 AND #21
#23	#1 OR #2 OR #22
#24	#9 AND #23
#25	#11 AND #14 AND #23
#26	#18 OR #19 OR #24 OR #25
	Date: 12.12.2017 Filters: Adult, Human, English & German, 2003 – to present

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review
Update	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments
Support:		
Sources	5a	Indicate sources of financial or other support for the review
Sponsor	5b	Provide name for the review funder and/or sponsor
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review

Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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Electronic Patient-Generated Health Data to Facilitate Prevention and Health Promotion: A Scoping Review Protocol

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Electronic Patient-Generated Health Data to Facilitate Prevention and Health Promotion: A Scoping Review Protocol

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ABSTRACT

Introduction: Rapidly expanding digital innovations transform the perception, reception and provision of health services. Simultaneously, health system challenges underline the need for patient-centered, empowering and citizen-engaging care, which facilitates a focus on prevention and health promotion. Through enhanced patient-engagement, patient-provider interactions and reduced information gaps, electronic Patient-Generated Health Data (PGHD) may facilitate both patient-centeredness and preventive scare. Despite that, comprehensive knowledge syntheses on their utilization for prevention and health promotion purposes are lacking. The review described in this protocol aims to fill that gap.

Methods and Analysis: Our methodology is guided by Arksey and O' Malley's methodological framework for scoping reviews, as well as its advanced version by Levac, Colquhoun and O'Brien. Seven electronic databases will be systematically searched using pre-defined keywords. Key electronic journals will be hand searched, while reference lists of included documents and grey literature sources will be screened thoroughly. Two independent reviewers will complete study selection and data extraction. One of the team's senior research members will act as a third reviewer and make the final decision on disputed documents. We will include literature with a focus on electronic PGHD and linked to prevention and health promotion. Literature on tertiary prevention, driven by existing discomfort or disability, goes beyond the review's scope and will be excluded. Analysis will be narrative and guided by Shapiro et al.'s adapted framework on PGHD flow.

Ethics and Dissemination: The scoping review described in this protocol aims to establish a baseline understanding of electronic PGHD generation, collection, communication, sharing, interpretation, utilization, context and impact for preventive purposes. The chosen methodology is based on the use of publicly available information and does not require ethical approval. Review findings will be disseminated in digital health conferences and symposia. Results will be published and additionally shared with relevant local and national authorities.

Keywords: preventive medicine, information technology, telemedicine, information management

STRENGHTS AND LIMITATIONS OF THIS STUDY

- A sensitive and comprehensive search strategy as well as a broader analytical scope will enable a holistic exploration of electronic PGHD use for prevention and health promotion, ultimately overcoming existing literature fragmentation
- The chosen multidimensional focus of the review's objectives, data extraction and synthesis goes beyond merely describing existing PGHD types, towards exploring the roles of those involved and their contexts, expanding the topic's conceptual understanding
- As the review's scope is restricted to disease prevention and health promotion, the resulting typology of electronic PGHD as well as the overall findings might not be applicable beyond those domains
- The chosen definition of electronic PGHD, which emphasizes the aspect of patient control and distinguishes them from standardized, provider-driven tools, will likely influence the results of this study
- Following accepted scoping review standards, the review will not formally assess the quality of included studies, thus, not allowing for statements on evidence strength

BACKGROUND

Emerging and continuously evolving digital innovations, such as wireless mobile devices, wearables, interactive online platforms and electronic data collection tools exert a transformative power on many domains of human action and interaction.[1, 2] With accelerating public interest in utilizing electronic tools for monitoring, managing and maintaining health and well-being, the healthcare market becomes an increasingly important field of current digital developments.[2] The literature often refers to a "revolutionary enabling" potential of digital innovations in facilitating the provision of care, carrying implications for patients, healthcare providers and policy makers.[3, 4]

Rapidly expanding digital ecosystems are defined as highly disruptive and key to improving healthcare, while reducing associated costs.[5] An illustrative example is the Internet of Things, broadly defined as the process of connecting and using various daily life objects via the internet.[6, 7] Those technological advances can facilitate the creation of valuable health information, as well as its effective use for enabling informed decision making and better outcomes.[4] Simultaneously, the penetration of interactive, dynamic and connected digital tools in daily living ultimately expands the roles of consumers, patients and care providers.[8] Individuals can quantify and track their health by digitally capturing vital parameters and behavioral data, while healthcare providers can potentially use information generated by new technologies to move beyond predominantly curative responsibilities and engage in pro-active, predictive and preventive action.[8]

Parallel and closely related to those new possibilities of capturing one's own health parameters is the emerging movement of patient-, or people-centered healthcare.[9,10] Traditionally, political decision makers and healthcare providers played predominant roles in shaping healthcare organization, management and provision.[9, 11] Modern healthcare systems could benefit from higher patient engagement, stronger communication channels, efficient information flows and

improved adoption of communication and information technologies.[12, 13] The Institute of Medicine aims to respond to those needs by emphasizing the importance of patient-centered care, defined as the provision of health services that are sensitively tailored around the needs and preferences of those who receive them.[14] The global strategy on people-centered care and integrated health services, prepared by the World Health Organization (WHO), underlines that a failure to shift towards predominantly consumer-focused practice will inevitably cause fragmentation, inefficiencies and long-term unsustainability.[9] Similarly, a conceptual model developed by Sholl et al. in 2014, highlights the importance of information exchange, active patient involvement and patient-empowerment.[15] Knowledge transfer, flow and accessibility of health data as well as the availability of adequate technology are core facilitators of patient-centered health services.[10] Finally, evidence suggests that patient-centeredness is associated with higher patient satisfaction and well-being, which in turn can act as mediating factors towards increased patient-engagement, health consciousness and improved health behavior.[16]

The phenomenon of electronic patient-generated health data (PGHD) can be positioned on the intersection between the digital revolution and the patient-centered care movement. A landmark whitepaper by the US Office of the National Coordinator for Health Information Technology defines PGHD as "*health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information—created, recorded, gathered, or inferred by or from patients or their designees (i.e., care partners or those who assist them) to help address a health concern*".[17, 18] Electronically captured, shared and utilized PGHD consists of digitally rooted information that is created outside traditional healthcare contexts.[17, 18] For example, diabetic patients can self-measure their blood glucose level at home and easily upload the results on interactive, provider-connected online platforms, enabling professional feedback as well as encouraging patient engagement and behavioral adaptation, action or change.[19] Similarly, cardiovascular disease patients can self-capture vital signs, such as blood pressure,

and rapidly transmit them via online-connected mobile phones. Data sharing can trigger specialist feedback whenever the recorded values deviate from pre-defined standards.[20] Those examples amplify the potential of digital health and PGHD as a resource in enabling convenient, patient-centered and cost-effective care, that is simultaneously pro-active, informed and prevention-focused.[18, 21]

STUDY RATIONALE

With increasing prevalence of chronic conditions, proactive and preventive action becomes increasingly vital for decision makers, providers as well as patients.[22] If implemented effectively, preventive care holds benefits for individuals, healthcare systems, businesses and society as such. It can reduce the risk of disease, discomfort and disability while diminishing avoidable expenditure, promoting a productive workforce and fostering healthy communities.[22] Achieving successful prevention ultimately requires a patient-centered approach that facilitates patient engagement and empowerment as well as meaningful patient-provider interactions.[22, 23]

Despite significant PGHD-related challenges, evidence suggests that digitally enabled PGHD utilization can facilitate both prevention and patient engagement, ultimately reducing unnecessary costs and inefficiencies.[12, 13, 17, 24-26] Furthermore, PGHD can add comprehensiveness to the assessment of an individual's health status by narrowing information gaps, enhancing patient-provider interaction and reducing data errors.[25-28] Research also indicates improved health literacy of patients and consumers, as well enhanced knowledge on health conditions and risks.[24]

Despite those benefits, systematically and comprehensively synthesized knowledge on electronic PGHD utilization for preventive and health promotion purposes appears to be lacking. Existing research is thematically fragmented, with most primary studies and reviews predominantly focusing on specific types of PGHD at a time. For example, the two scoping reviews by Archer et al. and Davis et

al. address PGHD in relation to personal health records and without a primary focus on prevention and health promotion.[29, 30] Other studies, such as the ongoing Cochrane review by Ammenwerth et al., capture PGHD as an additional functionality of electronic health records, retaining a predominant focus on patient access to provider-generated health information.[31] Further research syntheses outline the impacts of PGHD-linked tools, such as wearables and self-tracking devices, on specific risk factors and conditions. For example, Gierisch et al. summarized the effects of wearable sensing technologies on physical activity, Fu et al. reviewed the impact of mobile applications, including electronic monitoring and data transmission, on blood glucose levels, while Fletscher et al. explored the effects of blood pressure monitoring on health behaviors.[32-34] Existing reviews tend to focus on specific forms of PGHD and specific risk factors or conditions, often with reference to disease management. Our proposed review aims to depart from that "focused" approach to holistically address electronic PGHD and their use in preventive and health promoting activities. We hypothesize that approaching the literature with a broader lens and not limiting our focus to a specific PGHD format will ultimately enable a holistic understanding of where and how successfully PGHD are currently used. Finally, our analysis, being equally encompassing, may provide insights into how electronic PGHD are applied, adding to our knowledge on the contexts of PGHD utilization and how those might contribute to improvements and success.

STUDY OBJECTIVES

The overarching objective of the described study is to identify, map and synthesize existing knowledge on the generation, collection, communication, sharing, interpretation, utilization, context and impact of electronic PGHD for the facilitation and provision of prevention and health promotion. In order to achieve that, as well

as guide data extraction and synthesis, we have defined six targeted objectives, classified into three thematically linked components and outlined in table 1.

Table 1 Scoping Review Objectives

Overarching Objective: Identify, map and synthesize existing knowledge on the generation, collection, communication, sharing, interpretation, utilization, context and impact of electronic patient generated health data (PGHD) for the facilitation and/or provision of preventive activities and health promotion

First Targeted Objective: Provide an Overview of PGHD Types and Tools in the context of PGHD for prevention and health promotion

- Identify and map existing types and tools of electronic PGHD. The term "types" encompasses data properties and characteristics, as well as their preventive and health promoting aims and functions. The term "tools" denotes the utilized technical infrastructure for PGHD creation and utilization.

Second Targeted Objective: Explore the Roles of Patients/Consumers, Providers and Interactivity in the context of PGHD for prevention and health promotion

- **Patient/Consumer Roles:** Identify and synthesize existing data on patient/consumer roles, activities and literacy, as well as associated barriers and facilitators
- **Provider Roles:** Identify and synthesize existing data on provider roles, activities, literacy, the integration of such data in their practice, as well as associated barriers and facilitators
- **Interaction:** Identify and synthesize existing data that links the utilization of electronic PGHD to patient-provider or patient-technology interaction

Third Targeted Objective: Explore the Implications of PGHD on Health Outcomes and Equity Considerations, in the context of prevention and health promotion

- **Health Outcomes:** If available, synthesize existing data on the impacts of PGHD on prevention and health promotion related outcomes
- **Equity Considerations**: Identify whether and what proportion of identified literature addresses, explores or mentions actual or potential PGHD implications on health inequities, for example by addressing the digital divide, socio-demographic characteristics or disadvantaged population groups

The first targeted objective ultimately aims to enable an improved, comprehensive understanding of PGHD, while unifying a currently fragmented literature-base into a structured, practical typology. The second targeted objective aims to facilitate a conceptual understanding of how such data are utilized to offer preventive activities and health promotion, emphasizing on patient activities, provider roles and interactivity. Whenever available, we aim to additionally synthesize PGHD-related challenges, such as of financial, technical, practical and ethical nature. Current gaps in synthesized knowledge related to the utilization and impact of PGHD for prevention and health promotion purposes underline the importance of those elements. Closely related to that, the last objective aims to synthesize findings on potential impacts and implications of PGHD utilization on prevention and health promotion related outcomes as well as considerations regarding health equity. Acknowledging that differences in technological access, use and literacy may replicate social inequities in the digital domain, we consider it essential to capture any indication related to the potential or actual equity implications of electronic PGHD.[35] Finally, inherent to our overall aim of mapping and synthesizing existing knowledge, we expect to draw final conclusions on current research trends, as well as identify areas with further research needs.

METHODS AND ANALYSIS

Conceptual Model and Definitions

In order to guide and structure the scoping review process, we have adapted and utilized a conceptual framework that was prepared for the US office of the National Coordinator for Health Information Technology and reported in a 2012 White Paper.[17] The original framework visualizes the flow and context of PGHD, emphasizing on data capture, transfer and review.[17] Our adapted version,

provided in figure 1, retains the same flow, but additionally emphasizes the use of PGHD for fostering or providing disease prevention, health promotion and patient-provider or patient-technology interactions. The framework visualizes the generation of different health data types by patients, as well as their collection, sharing, communication and use.

Figure 1: Adapted Framework for PGHD Flow and Context for Prevention and Health Promotion.[17]

For the purposes of this study, we propose a more comprehensive definition of electronic PGHD. Accordingly, the term emphasizes digitally rooted "*health-related data- including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information—created, recorded, gathered, or inferred by or from patients or their designees (i.e., care partners or those who assist them) to help address a health concern*", captured outside traditional healthcare contexts and being distinct from other forms of patient-provided data, such as patient-reported outcomes (PROs).[17, 36] PROs are commonly informed, standardized and driven by healthcare providers, lacking the level of patient control that is characteristic for PGHD.[17, 36] Thus, responsibility for capturing, recording and sharing electronic PGHD lies with the patients.[17]

The World Health Organization (WHO) defines health promotion as any activity that aims to empower people in achieving control over and enhancing their health.[37] Prevention is defined as any activity that intentionally aims to impede, reduce or delay the occurrence or progress of physical or mental ill health, injury and premature death.[38] We will not differentiate between primary and secondary prevention, acknowledging that the boundaries are neither strictly defined nor clear, especially when it comes to complex chronic conditions.[39] However, preventive measures categorized as "tertiary", driven by an already existing severe discomfort or disability, go beyond the review's scope.[39] The reasoning is supported by

conceptual and practical arguments. Conceptually, we follow Gordon's classification, that restricts the term prevention to primary and secondary levels. On the other hand, tertiary prevention follows after disease manifestation , which is in turn driven by different dynamics and often non-distinguishable from therapeutic activities.[39] Practically, not keeping preventive and therapeutic interventions apart would enormously broaden up our review's scope and lead to an unmanageable amount of literature.

The term provider is defined as any professional that is responsible for offering health-related services, including health behavior and lifestyle changes (e.g. primary care physicians, primary care nurses, pharmacists, specialist physicians, physiotherapists, psychologists, wellness providers, health and lifestyle coaches). This comprehensive definition aims to maintain a relatively broad scope and reduce the likelihood of missing potential valuable literature. The review will also incorporate studies where healthcare or wellness providers hold secondary roles, such as merely monitoring electronic PGHD, or providing input on the development of preventive digital PGHD-based tools, without direct interaction with patients. Even though the patient-provider interaction and provider involvement might be weak in such scenarios, they are crucial to fully understand the different approaches in using electronic PGHD for preventing disease and promoting health. Finally, table 2 outlines all PGHD dimensions targeted by our review, attaching those to corresponding questions and hypothetical examples.

Table 2 Targeted PGHD Dimensions

Dimension	Corresponding Question & [hypothetical example]
PGHD generation	How are PGHD created? [using a digital monitor to self-measure blood pressure]
PGHD collection	How are PGHD captured and stored [storing collected blood pressure values in an online patient portal]

PGHD communication & sharing	How are PGHD transferred? [using the patient portal to transfer blood pressure data to the general practitioner via secure e-mail services]
PGHD interpretation	How are PGHD reviewed and made sense of? [patient/provider views uploaded blood pressure measurements online over time to understand progress]
PGHD utilization	How are PGHD applied for achieving desired results? [online portal sends provider-initiated feedback E-Mails, based on abnormal values]
PGHD context	What are settings/environments of PGHD use? [electronic blood pressure measurements taken at home and at the work space]
PGHD impact	What are the effects or implications of PGHD? [control and course of blood pressure]

Protocol Structure

This protocol is structured and guided by Arksey and O'Malley's methodological framework for scoping studies, as well as Levac, Colquhoun and O'Brien's work on advancing that methodology.[40, 41] The following six sections are categorized according to the elements of that framework. Those include identifying the research question (Step 1), identifying relevant studies (Step 2), study selection (Step 3), charting the data (Step 4), collating, summarizing and reporting the results (Step 5) and stakeholder consultations (Step 6).[40, 41] Furthermore, this protocol follows the reporting guidelines of the PRISMA-P checklist for systematic review protocols.[42] Falling beyond the scope of a scoping review, the three PRISMA-P elements let aside are the risk of bias assessment, meta-biases and evidence strength (GRADE).[42]

Step 1: Identifying Research Question

Arksey and O'Malley describe the definition of an appropriate research question as a crucial initial step that defines and refines the chosen research strategy.[40] An iterative process of exchange, consultation and literature acquaintance led the development of the review's guiding questions. An expert has been consulted to provide further input and feedback on our predefined set of core and sub-questions. In line with our intention to comprehensively map and synthesize a potentially fast-growing and fragmented volume of literature on electronic PGHD, the review's primary, overarching research question is defined as: "*What is our knowledge status, retrieved from existing literature, on the generation, collection, communication, sharing, interpretation, utilization, context and impact of electronic PGHD for the facilitation of patient/consumer-centered preventive activities and health promotion?"*. Our question is focused on prevention or health promotion targets adults. A comparator is not defined, as our search will not be restricted to studies with controls.

Step 2: Identifying relevant studies

The identification of relevant literature will consist of several combined approaches, including electronic database searches and complementary activities, such as hand searches of selected online journals, relevant webpages, grey literature sources, reference list screening and expert consultations. Initially, we will systematically search 7 electronic databases, including Medline, CINAHL, PsycInfo, Scopus, Web of Science, EMBASE and IEEE Digital Library. Preliminary literature searches, consultation of thematically related reviews, input from the research team and the support of a specialized librarian led to pre-defined, preliminary search strategy, created on EMBASE and provided in supplementary file 1. Our strategy is purposively sensitive, entailing a variety of keywords related to PGHD, restricted to adult populations and research published in the last 15 years. Limiting our research to the last 15 years is based on our preliminary searches, that indicate an emergence and accumulation of relevant literature during the last decade. We purposively added another five years to ensure that we capture all valuable literature and trends.

The final strategy will be refined in a consultation with the experienced librarian, who will run all searches. Retrieved documents will be imported into the electronic citation manager Mendeley.

In order to acquire the level of comprehensiveness required for a scoping review, we will also hand search key electronic journals, including JAMIA, JIMR, the International Journal of Digital Healthcare, Digital Health (SAGE) and the Journal of m-Health.[40] Grey literature, such as reports, policy briefs, conference abstracts and theses will be retrieved through rigorous searches of the following sources: Grey Literature Report, Open Grey, Web of Science Conference Proceedings and Proquest Dissertations. Ensuring that no relevant publication is missed, we will run several web engine searches using Google, Google Scholar and Yahoo and screening the first ten result pages. Furthermore, we will screen thematically relevant webpages, such as the Office of the National Coordinator for Health Information Technology (ONC), the Healthcare Information and Management Systems Society (HIMSS), the Patient-Centered Outcomes Research Institute, the Research Triangle Institute International, the Agency for Healthcare Research and Quality (AHRQ) and Digital Health Canada. Our last research step consists of the manual reference list screening of all eligible studies as well as author consultations, requesting input on potentially missed or unpublished work.

Step 3: Study Selection

The study selection process will consist of two phases, independently conducted by two members of the research team. The first author of this protocol, having previous experience with literature reviews and an educational background in digital health interventions for disease prevention purposes, will take the first reviewer role. The second reviewer will be recruited based on substantial experience in planning and conducting literature reviews, an educational background in a health-related discipline and a good understanding of the proposed topic, preferably with previous work experience in a PGHD-related topic. Both will be responsible for

independently completing the screening, selection and data extraction process, with the first reviewer having the added responsibility of data synthesis and final manuscript preparation. The first study selection phase includes the title and abstract screening of all identified documents. The second phase consists of full-text review of studies that have been classified as potentially eligible during phase one. During both phases, reviewers will assess study inclusion against a set of pre-defined eligibility criteria. To be eligible, studies have to have a clear focus on electronic PGHD, be linked to disease prevention and health promotion, address adult populations and include some reference to patient and provider involvement. The absence of elements or indicators referring to prevention and health promotion (e.g. reduction of blood pressure) or a shallow exploration of patient or provider attitudes towards PGHD and PGHD-based tools, without being clearly defined within a prevention or health promotion context, will lead to exclusion. To ensure that the chosen eligibility criteria are sensitive and clear in capturing relevant documents, they will be pre-tested by both reviewers on a sample of studies that have been identified during preliminary searches. Maintaining a broad scope, our review will consider any type of primary research study designs as well as grey literature. Relevant systematic reviews will be considered as sources of potentially valuable primary research.

We will assess inter-rater agreement during both phases, using Cohen's k coefficient.[43] The coefficient, calculated after screening the first 50 titles and abstracts, will act as an indicator of whether both reviewers understand and apply the inclusion criteria in an equal, correct and coherent manner. Low agreement (<0.40) will be followed by a consultation of the two reviewers, and if needed, adjustment or rewording of the eligibility criteria. This process will be repeated for the next 50 titles and abstracts and until interrater agreement reaches substantial levels (>0.40). After the title and abstract screening is completed, the two reviewers will meet to compare their results. Consulting the inclusion and exclusion criteria, they will try to resolve conflicts and reach consensus on eligibility for full-text

review. Studies that are unclear and do not allow for consensus will also enter full-text screening. During full-text review, which will be independently completed by the same two reviewers, interrater agreement will be calculated for the first 15 studies. After completion of full-text screening, reviewers will meet again to compare their results. All discordant articles will be reexamined and persisting disputes will be resolved through consultation with a third reviewer, selected among one of the senior members of the research team (MM, MP) and being responsible for the final decision on disputed papers. Both are members of Cochrane Public Health Europe and have considerable thematic and methodological knowledge. To ensure the highest levels of process transparency and reproducibility, the entire process will be captured and visualized in a PRISMA flow chart, including the most common exclusion reasons, as well as the final number of included documents.[44]

Table 3 provides the selected exclusion criteria, carefully chosen to guide the identification of eligible studies, while counterbalancing the relatively high sensitivity that is inherent to the review's broad research question. Documents that fulfil one or more of the statements below will be excluded.

Table 3 Exclusion Criteria

1. Does not address the generation, collection, communication, sharing, interpretation, utilization, context or impact of electronic PGHD (as outlined in Table 2)
2. Lacks a focus on prevention and health promotion (e.g. exclusively addresses rehabilitation or therapeutic interventions)
3. Addresses patient-generated information that is not personal health-related
4. Does not describe, explore and analyse some form of patient and provider involvement
5. Does not address or include adults
6. Written in a language other than English or German

Step 4: Charting the data

Data extraction will be conducted independently by two reviewers, guided by a pre-defined, however flexible data extraction form. The preliminary form is developed by the research team and shown in table 4. It aims to ensure that all required

information is captured practically, efficiently and accurately, minimizing the risk of missing information. Arksey and O'Malley's methodological framework suggests charting the data according to central research themes.[40] Thus, the chosen data-extraction elements have been developed in line with the review's objectives and corresponding research questions. Next to general information, we aim to retrieve data on PGHD types, patient and provider responsibilities, PGHD impacts on disease prevention and health promotion and equity.

The final form will be refined and validated through consultations with the entire research team, as well as expert feedback. As suggested by Levac et al. and Daudt et al., the form will be initially and independently tested by two reviewers on a random sample of five studies.[41, 45] This phase is described as as key to improving the quality and applicability of the data extraction chart.[45] It will be followed by consultation to ensure accuracy, consistency and that the captured information contributes to the study's research questions. Consultation might finally lead to form modifications that have to be reviewed and agreed upon by the entire research team.

After completion of the full data extraction process, both reviewers' final data-sets will be compared. Each article will have a unique identification number to enhance process efficiency and practicality. Inconsistencies and disagreements will be discussed, re-consulting the respective documents and if necessary, requesting support by a senior investigator of the team (MM, MP).

Table 4 Preliminary Data Charting Elements

Element & Sub-element	Associated Question
Publication Details	
Author & Affiliation	Who wrote the study/document?
Type	Is the document an empirical study or grey literature?
Year	What year was the study/document published?
Country/Region	Which country is the study/document focusing on?
Funding	Are the funding sources provided?
Conflict of Interest Declaration	Is a conflict of interest statement included?
General Details	
Methodological Design	What is the study/document design?
Aims	What are the study/document aims?
Population	Which is the target population of the study/document?
Addressed condition(s), risk factors(s), symptom(s), behavior(s) or outcome measure(s)	What is the health-related focus of the study/document?
Setting	What is the described setting?
Perspective (Promotion/Prevention)	Is the focus on prevention or health promotion?
Content	
Patient Roles and Activities ➢ PGHD generation ➢ PGHD transfer & use ➢ Context ➢ Barriers & Facilitators	What are the patient roles and required activities in generating, transferring and using electronic patient-generated health data (PGHD) for prevention/health promotion purposes?
PGHD Types ➢ Architecture ➢ Aims and Purposes	What types of PGHD are addressed? What PGHD-based tools are used?
Provider Roles and Activities ➢ PGHD Integration ➢ PGHD use ➢ Context ➢ Barriers & Facilitators	What are the provider roles and required activities in integrating and using electronic PGHD for prevention/health promotion purposes?

Interactivity ➢ Barriers & Facilitators	How do electronic PGHD affect or relate to patient-provider, as well as patient-technology interaction?
Impact on Prevention and Health Promotion-Related Outcomes	What is the impact of electronic PGHD use on any outcomes related to prevention and health promotion?
Equity Considerations	Does the study/document address, explore or refer to actual or potential equity-related implications of PGHD? (e.g. better results for disadvantaged social groups)
Other Important Results	Further important results?

Step 5: Collating, summarizing and reporting the results

As described by Arksey and O'Malley, a weighted data synthesis and aggregation of findings is not inherently essential to a scoping review, considering the missing assessment of evidence quality and robustness.[40] The chosen analytical approach will therefore be of narrative nature, guided by the adapted PGHD-flow framework (figure 1) and the review's objectives.[17] Despite its benefits, a quality assessment will not be performed as it does not align with our aim of scoping a potentially large and heterogeneous literature volume.

Initial synthesis will be of basic quantitative nature, summarizing the extent, scope and nature of existing literature. Publication types, years, geographic distribution, target populations, target conditions, risks and behaviors, as well as existing methodologies will be synthesized descriptively, using ranges and counts, presented in tables. That step will provide an overview of existing evidence and research activity trends, as well as highlight potential research gaps.[40]

Further synthesis will remain narrative, but also consider quantitative primary data. Tables and figures will summarize key findings, structured around the review's objectives. The research team and experts will enrich data synthesis through regular input, ensuring validity and transparency. With exception of the risk of bias and evidence strength (GRADE) assessment, the reporting of our results will be guided by the PRISMA reporting guidelines.[46] The entire process, including screening (Step 3), data extraction (Step 4) and synthesis will be conducted

with the Covidence Software and Excel. We are not planning any additional analyses.

Step 6: Consultation

Levac et al., pointed out that consultation, the sixth, transversal optional stage of the scoping studies framework, may enable stakeholder engagement and provide valuable input, beyond the information provided in the literature.[41] As already described throughout the protocol, expert consultation is central at all stages of this study. An external expert in the area of PGHD has been consulted twice during the development of this protocol, providing conceptual and content-related feedback and advice. During the review process, we will additionally establish regular consultation with one provider-partner and at least one patient-partner. Both stakeholders will be asked to provide feedback during data extraction, appraisal of preliminary results, data synthesis and interpretation. Finally, we aim to engage digital health experts within the team's own institution for additional advice. All involved experts and stakeholders will be acknowledged in the final publication.

Patient and Public Involvement

There was no patient or public involvement in the design of this protocol. Nonetheless, as outlined in the previous paragraph, at least one patient advisor will be consulted during the implementation stages of our review, asked to provide feedback on the clarity, applicability and value of the review's findings and interpretations. Any involved patient-partner will receive our preliminary and final results electronically and during consultations.

ETHICS AND DISSEMINATION

The described review constitutes the first step of a larger research project on digital solutions for disease prevention and health promotion. Its results ultimately fulfill

the function of establishing a comprehensive conceptual knowledge of electronic PGHD and will be used to inform prospective research steps. Initiation of screening and data collection is planned for February 2018. Findings will be disseminated at relevant conferences and symposia. Results will be published and additionally shared with our provider and patient-partners and their networks, as well as local and national organizations operating in the field of digital health. As our methodology is based on the review of publicly available information, ethical approval is not required. Any amendments to this protocol will be documented precisely and listed in the final review publication.

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Authors' contributions: Vasileios Nittas contributed to the conceptualization of the study, wrote and edited the manuscript. Margot Mütsch contributed to the conceptualization of the study, supervised the entire process and edited the manuscript. Milo Puhan contributed to the conceptualization of the study, supervised the entire process and edited the manuscript. Frederic Ehrler provided regular input and edited the manuscript. All authors provided final approval of the final protocol version.

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Competing interests statement. We have read and understood the BMJ policy on the declaration of interests and declare that we have no competing interests.

Data sharing statement: No additional data available.

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Figure Legends

Figure 1: Adapted Framework for Patient-Generated Health Data (PGHD) Flow and Context for Prevention and Health Promotion.[17]. The Framework visualizes the flow of PGHD from the patient/consumer (generation & collection stages), passing through intermediaries (communication, sharing & interpretation stages) and back to the patient in form of prevention, health promotion and interaction (utilization & impact stages).

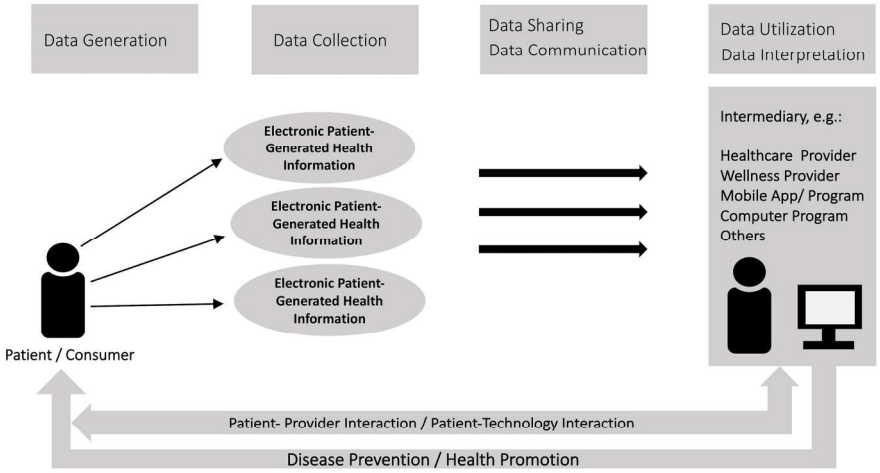

Figure 1: Adapted Framework for Patient-Generated Health Data (PGHD) Flow and Context for Prevention and Health Promotion.[17]. The Framework visualizes the flow of PGHD from the patient/consumer (generation & collection stages), passing through intermediaries (communication, sharing & interpretation stages) and back to the patient in form of prevention, health promotion and interaction (utilization & impact stages).

190x107mm (300 x 300 DPI)

Supplementary File 1: Preliminary Search Strategy, piloted on EMBASE

#1	((patient NEXT/1 (reported OR shared) NEAR/3 (data OR information)):ti,ab) OR (((consumer OR people OR user OR person*) NEXT/1 reported NEAR/6 (health OR medical OR clinical) NEXT/1 (information OR data)):ti,ab) OR ((connected NEXT/1 (health OR medicine)):ti,ab)
#2	((patient NEXT/3 portal):ti,ab) OR (((electronic OR digital OR online OR web* OR internet) NEXT/3 'health diary'):ti,ab)
#3	'electronic patient record'/exp OR 'electronic medical record'/exp OR 'electronic health record'/de OR 'telemedicine'/exp OR (((personal OR user OR consumer OR electronic OR online OR digital OR web OR internet OR computer) NEAR/1 (medical OR health OR clinical) NEXT/1 record):ti,ab) OR ((patient* NEXT/3 record):ti,ab
#4	((patient OR consumer OR people OR user OR person* OR self*) NEXT/1 (generated OR reported OR shared)):ti,ab
#5	self:ti,ab OR oneself:ti,ab OR himself:ti,ab OR herself:ti,ab OR personal*:ti OR connected:ti,ab OR ((personal* NEXT/3 (health* OR medicine* OR care OR manag* OR monitor*)):ti,ab)
#6	#4 OR #5
#7	#3 AND #6
#8	#1 OE #2 OR #7
#9	promot*:ti OR prevent*:ti OR improve*:ti OR (((health OR patient) NEAR/3 (educat* OR communicat* OR advocacy OR literacy OR behaviour OR behavior OR status)):ti) OR (((disease OR health OR personalized) NEXT/3 manag*):ti) OR ((self NEXT/1 (manag* OR monitor*)):ti)
#10	#8 AND #9
#11	'health promotion'/exp OR 'health literacy'/exp OR 'health education'/exp OR 'disease management'/exp OR 'health behavior'/exp OR 'health status'/exp OR ((health NEAR/1 (promot* OR prevent* OR educat* OR communicat* OR advocacy OR literacy OR behaviour OR status)):ti,ab) OR ((disease NEAR/1 manag*):ti,ab) OR (((disease OR medicine) NEAR/3 prevent*):ti,ab) OR ((self NEXT/1 (manag* OR monitor*)):ab)
#12	'devices'/exp OR 'internet'/exp OR 'information processing'/exp OR (((electronic* OR mobile OR smart) NEXT/3 (tool* OR watch* OR device* OR gadget* OR bracelet* OR pager* OR monitor*)):ti,ab) OR (((mobile OR cell OR smart) NEXT/3 phone):ti,ab) OR tablet*:ti,ab OR iphone*:ti,ab OR ipad*:ti,ab OR smartphone*:ti,ab OR wearable*:ti,ab OR app:ti,ab OR apps:ti,ab OR application*:ti,ab OR ((technol* NEAR/3 (consumer OR patient OR user)):ti,ab)
#13	innovat*:ti,ab
#14	#12 OR #13
#15	#8 AND #11 AND #14
#16	#8 AND #11 AND #12
#17	#10 OR #15

#18	((patient NEXT/1 generated NEAR/3 (data OR information)):ti,ab) OR (((consumer OR people OR user OR person*) NEXT/1 generated NEAR/6 (health OR medical OR clinical) NEXT/1 (information OR data)):ti,ab) OR ((connected NEXT/1 (health OR medicine)):ti,ab)
#19	(connected NEXT/1 (health* OR medicine OR treat* OR monitor* OR care*)):ti,ab
#20	#17 OR #18 OR #19
#21	'electronic patient record'/exp OR 'electronic medical record'/exp OR 'electronic health record'/de OR 'telehealth'/exp OR 'medical informatics'/exp OR (((personal OR user OR consumer OR electronic OR online OR digital OR web OR internet OR computer) NEAR/1 (medical OR health OR clinical) NEXT/1 record):ti,ab) OR ((patient* NEXT/3 record):ti,ab) OR (((electronic OR digital OR mobile OR tele) NEXT/1 (health OR care OR monitoring)):ti,ab) OR 'e health':ti,ab OR 'm health':ti,ab OR 'e care':ti,ab OR 'm care':ti,ab OR 'e monitoring':ti,ab OR 'm monitoring':ti,ab OR 'internet of things':ti,ab OR telemedicine:ti,ab OR ((health NEXT/1 (it OR 'information technology')):ti,ab)
#22	#6 AND #21
#23	#1 OR #2 OR #22
#24	#9 AND #23
#25	#11 AND #14 AND #23
#26	#18 OR #19 OR #24 OR #25
	Date: 12.12.2017 Filters: Adult, Human, English & German, 2003 – to present

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review
Update	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments
Support:		
Sources	5a	Indicate sources of financial or other support for the review
Sponsor	5b	Provide name for the review funder and/or sponsor
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review

Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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Electronic Patient-Generated Health Data to Facilitate Prevention and Health Promotion: A Scoping Review Protocol

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ABSTRACT

Introduction: Rapidly expanding digital innovations transform the perception, reception and provision of health services. Simultaneously, health system challenges underline the need for patient-centered, empowering and citizen-engaging care, which facilitates a focus on prevention and health promotion. Through enhanced patient-engagement, patient-provider interactions and reduced information gaps, electronic Patient-Generated Health Data (PGHD) may facilitate both patient-centeredness and preventive scare. Despite that, comprehensive knowledge syntheses on their utilization for prevention and health promotion purposes are lacking. The review described in this protocol aims to fill that gap.

Methods and Analysis: Our methodology is guided by Arksey and O' Malley's methodological framework for scoping reviews, as well as its advanced version by Levac, Colquhoun and O'Brien. Seven electronic databases will be systematically searched using pre-defined keywords. Key electronic journals will be hand searched, while reference lists of included documents and grey literature sources will be screened thoroughly. Two independent reviewers will complete study selection and data extraction. One of the team's senior research members will act as a third reviewer and make the final decision on disputed documents. We will include literature with a focus on electronic PGHD and linked to prevention and health promotion. Literature on prevention that is driven by existing discomfort or disability goes beyond the review's scope and will be excluded. Analysis will be narrative and guided by Shapiro et al.'s adapted framework on PGHD flow.

Ethics and Dissemination: The scoping review described in this protocol aims to establish a baseline understanding of electronic PGHD generation, collection, communication, sharing, interpretation, utilization, context and impact for preventive purposes. The chosen methodology is based on the use of publicly available information and does not require ethical approval. Review findings will be disseminated in digital health conferences and symposia. Results will be published and additionally shared with relevant local and national authorities.

Keywords: preventive medicine, information technology, telemedicine, information management

STRENGHTS AND LIMITATIONS OF THIS STUDY

- A sensitive and comprehensive search strategy as well as a broader analytical scope will enable a holistic exploration of electronic PGHD use for prevention and health promotion, ultimately overcoming existing literature fragmentation
- The chosen multidimensional focus of the review's objectives, data extraction and synthesis goes beyond merely describing existing PGHD types, towards exploring the roles of those involved and their contexts, expanding the topic's conceptual understanding
- As the review's scope is restricted to health promotion and certain dimensions of prevention, the resulting typology of electronic PGHD as well as the overall findings might not be applicable beyond those domains
- The chosen definition of electronic PGHD, which emphasizes the aspect of patient control and distinguishes them from standardized, provider-driven tools, will likely influence the results of this study
- Following accepted scoping review standards, the review will not formally assess the quality of included studies, thus, not allowing for statements on evidence strength

BACKGROUND

Emerging and continuously evolving digital innovations, such as wireless mobile devices, wearables, interactive online platforms and electronic data collection tools exert a transformative power on many domains of human action and interaction.[1, 2] With accelerating public interest in utilizing electronic tools for monitoring, managing and maintaining health and well-being, the healthcare market becomes an increasingly important field of current digital developments.[2] The literature often refers to a "revolutionary enabling" potential of digital innovations in facilitating the provision of care, carrying implications for patients, healthcare providers and policy makers.[3, 4]

Rapidly expanding digital ecosystems are defined as highly disruptive and key to improving healthcare, while reducing associated costs.[5] An illustrative example is the Internet of Things, broadly defined as the process of connecting and using various daily life objects via the internet.[6, 7] Those technological advances can facilitate the creation of valuable health information, as well as its effective use for enabling informed decision making and better outcomes.[4] Simultaneously, the penetration of interactive, dynamic and connected digital tools in daily living ultimately expands the roles of consumers, patients and care providers.[8] Individuals can quantify and track their health by digitally capturing vital parameters and behavioral data, while healthcare providers can potentially use information generated by new technologies to move beyond predominantly curative responsibilities and engage in pro-active, predictive and preventive action.[8]

Parallel and closely related to those new possibilities of capturing one's own health parameters is the emerging movement of patient-, or people-centered healthcare.[9,10] Traditionally, political decision makers and healthcare providers played predominant roles in shaping healthcare organization, management and provision.[9, 11] Modern healthcare systems could benefit from higher patient engagement, stronger communication channels, efficient information flows and

improved adoption of communication and information technologies.[12, 13] The Institute of Medicine aims to respond to those needs by emphasizing the importance of patient-centered care, defined as the provision of health services that are sensitively tailored around the needs and preferences of those who receive them.[14] The global strategy on people-centered care and integrated health services, prepared by the World Health Organization (WHO), underlines that a failure to shift towards predominantly consumer-focused practice will inevitably cause fragmentation, inefficiencies and long-term unsustainability.[9] Similarly, a conceptual model developed by Sholl et al. in 2014, highlights the importance of information exchange, active patient involvement and patient-empowerment.[15] Knowledge transfer, flow and accessibility of health data as well as the availability of adequate technology are core facilitators of patient-centered health services.[10] Finally, evidence suggests that patient-centeredness is associated with higher patient satisfaction and well-being, which in turn can act as mediating factors towards increased patient-engagement, health consciousness and improved health behavior.[16]

The phenomenon of electronic patient-generated health data (PGHD) can be positioned on the intersection between the digital revolution and the patient-centered care movement. A landmark whitepaper by the US Office of the National Coordinator for Health Information Technology defines PGHD as "*health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information—created, recorded, gathered, or inferred by or from patients or their designees (i.e., care partners or those who assist them) to help address a health concern*".[17, 18] Electronically captured, shared and utilized PGHD consists of digital information that is created outside traditional healthcare contexts.[17, 18] For example, individuals at high risk of chronic disease, such as sedentary and overweight adults can self-monitor their physical activity at home and easily share their records on interactive, provider-connected online platforms, enabling professional feedback and guidance.[19] Similarly, they can self-capture overall health parameters, such as blood pressure, body fat or weight and rapidly transmit

their measuring values via online-connected devices. Data sharing can trigger personalized feedback, customized health plans and other persuasive health promotion techniques.[20] Those examples amplify the potential of digital health and PGHD as a resource in enabling convenient, person-centered and cost-effective care, that is simultaneously pro-active, informed and prevention-focused.[18, 21] Despite this study's focus on prevention and health promotion, its crucial to acknowledge the importance and applicability of electronic PGHD beyond those domains. In fact, such data can facilitate the treatment and rehabilitation of increasingly prevalent chronic conditions, such as diabetes and heart failure [17]. The justification for our limited scope has conceptual and practical reasons, outlined in the methods section. A more comprehensive and detailed definition of electronic PGHD is also outlined in the methods section of this protocol.

STUDY RATIONALE

With increasing prevalence of chronic conditions, proactive and preventive action becomes increasingly vital for decision makers, providers as well as patients.[22] If implemented effectively, preventive care holds benefits for individuals, healthcare systems, businesses and society as such. It can reduce the risk of disease, discomfort and disability while diminishing avoidable expenditure, promoting a productive workforce and fostering healthy communities.[22] Achieving successful prevention ultimately requires a patient-centered approach that facilitates patient engagement and empowerment as well as meaningful patient-provider interactions.[22, 23]

Despite significant PGHD-related challenges, evidence suggests that digitally enabled PGHD utilization can facilitate both prevention and patient engagement, ultimately reducing unnecessary costs and inefficiencies.[12, 13, 17, 24-26] Furthermore, PGHD can add comprehensiveness to the assessment of an individual's health status by narrowing information gaps, enhancing patient-provider interaction and reducing data errors.[25-28] Research also indicates

improved health literacy of patients and consumers, as well enhanced knowledge on health conditions and risks.[24]

Despite those benefits, systematically and comprehensively synthesized knowledge on electronic PGHD utilization for preventive and health promotion purposes appears to be lacking. Existing research is thematically fragmented, with most primary studies and reviews predominantly focusing on specific types of PGHD at a time. For example, the two scoping reviews by Archer et al. and Davis et al. address PGHD in relation to personal health records and without a primary focus on prevention and health promotion.[29, 30] Other studies, such as the ongoing Cochrane review by Ammenwerth et al., capture PGHD as an additional functionality of electronic health records, retaining a predominant focus on patient access to provider-generated health information.[31] Further research syntheses outline the impacts of PGHD-linked tools, such as wearables and self-tracking devices, on specific risk factors and conditions. For example, Gierisch et al. summarized the effects of wearable sensing technologies on physical activity, Fu et al. reviewed the impact of mobile applications, including electronic monitoring and data transmission, on blood glucose levels, while Fletscher et al. explored the effects of blood pressure monitoring on health behaviors.[32-34] Existing reviews tend to focus on specific forms of PGHD and specific risk factors or conditions, often with reference to disease management. Our proposed review aims to depart from that "focused" approach to holistically address electronic PGHD and their use in preventive and health promoting activities. We hypothesize that approaching the literature with a broader lens and not limiting our focus to a specific PGHD format will ultimately enable a holistic understanding of where and how successfully PGHD are currently used. Finally, our analysis, being equally encompassing, may provide insights into how electronic PGHD are applied, adding to our knowledge on the contexts of PGHD utilization and how those might contribute to improvements and success. Achieving that requires a clear framing, for which this protocol provides clear definitions of key terms and concepts.

STUDY OBJECTIVES

The overarching objective of the described study is to identify, map and synthesize existing knowledge on the generation, collection, communication, sharing, interpretation, utilization, context and impact of electronic PGHD for the facilitation and provision of prevention and health promotion. In order to achieve that, as well as guide data extraction and synthesis, we have defined six targeted objectives, classified into three thematically linked components and outlined in table 1.

Table 1 Scoping Review Objectives

Overarching Objective: Identify, map and synthesize existing knowledge on the generation, collection, communication, sharing, interpretation, utilization, context and impact of electronic patient generated health data (PGHD) for the facilitation and/or provision of preventive activities and health promotion
First Targeted Objective: Provide an Overview of PGHD Types and Tools in the context of PGHD for prevention and health promotion ➢ Identify and map existing types and tools of electronic PGHD. The term "types" encompasses data properties and characteristics, as well as their preventive and health promoting aims and functions. The term "tools" denotes the utilized technical infrastructure for PGHD creation and utilization.
Second Targeted Objective: Explore the Roles of Patients/Consumers, Providers and Interactivity in the context of PGHD for prevention and health promotion ➢ **Patient/Consumer Roles:** Identify and synthesize existing data on patient/consumer roles, activities and literacy, as well as associated barriers and facilitators ➢ **Provider Roles:** Identify and synthesize existing data on provider roles, activities, literacy, the integration of such data in their practice, as well as associated barriers and facilitators ➢ **Interaction:** Identify and synthesize existing data that links the utilization of

electronic PGHD to patient-provider or patient-technology interaction

Third Targeted Objective: Explore the Implications of PGHD on Health Outcomes and Equity Considerations, in the context of prevention and health promotion

- **Health Outcomes:** If available, synthesize existing data on the impacts of PGHD on prevention and health promotion related outcomes
- **Equity Considerations**: Identify whether and what proportion of identified literature addresses, explores or mentions actual or potential PGHD implications on health inequities, for example by addressing the digital divide, socio-demographic characteristics or disadvantaged population groups

The first targeted objective ultimately aims to enable an improved, comprehensive understanding of PGHD, while unifying a currently fragmented literature-base into a structured, practical typology. The second targeted objective aims to facilitate a conceptual understanding of how such data are utilized to offer preventive activities and health promotion, emphasizing on patient activities, provider roles and interactivity. Whenever available, we aim to additionally synthesize PGHD-related challenges, such as of financial, technical, practical and ethical nature. Current gaps in synthesized knowledge related to the utilization and impact of PGHD for prevention and health promotion purposes underline the importance of those elements. Closely related to that, the last objective aims to synthesize findings on potential impacts and implications of PGHD utilization on prevention and health promotion related outcomes as well as considerations regarding health equity. Acknowledging that differences in technological access, use and literacy may replicate social inequities in the digital domain, we consider it essential to capture any indication related to the potential or actual equity implications of electronic PGHD.[35] Finally, inherent to our overall aim of mapping and synthesizing existing knowledge, we expect to draw final conclusions on current research trends, as well as identify areas with further research needs.

METHODS AND ANALYSIS

Conceptual Model and Definitions

In order to guide and structure the scoping review process, we have adapted and utilized a conceptual framework that was prepared for the US office of the National Coordinator for Health Information Technology and reported in a 2012 White Paper.[17] The original framework visualizes the flow and context of PGHD, emphasizing on data capture, transfer and review.[17] Our adapted version, provided in figure 1, retains the same flow, but additionally emphasizes the use of PGHD for fostering or providing disease prevention, health promotion and patient-provider or patient-technology interactions. The framework visualizes the generation of different health data types by patients, as well as their collection, sharing, communication and use.

Figure 1: Adapted Framework for PGHD Flow and Context for Prevention and Health Promotion.[17]

For the purposes of this study, we propose a more precise definition of electronic PGHD. Accordingly, the term emphasizes digital "*health-related data- including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information—created, recorded, gathered, or inferred by or from patients or their designees (i.e., care partners or those who assist them) to help address a health concern"* and are captured outside traditional healthcare contexts. Our definition is limited to predominantly patient or consumer driven PGHD, being distinct from data collected through standardized, provider-driven questionnaires.[17, 36] Thus, responsibility for capturing, recording and sharing electronic PGHD lies with the patients and consumers.[17] We justify that focus on the very nature of prevention and health

promotion, which requires an empowered healthcare consumer. To comply with our definition, PGHD should be available in a digital format when utilized for the intended health-related purposes.

The World Health Organization (WHO) defines health promotion as any activity that aims to empower people in achieving control over and enhancing their health.[37] Prevention is defined as any activity that intentionally aims to impede, reduce or delay the occurrence or progress of physical or mental ill health, injury and premature death.[38] Acknowledging that the boundaries between primary, secondary and tertiary prevention, as well as their definitions are neither strictly defined nor clear, especially when it comes to complex chronic conditions, we set our study's limits around three precise prevention elements and health promotion.[39] Thus, to fall within the review's scope, studies require to be placed in the context of at least one of the following prevention domains: (1) preventing initial occurrence of disease in healthy or high-risk individuals, (2) mitigating risk in healthy or high-risk individuals, (3) monitoring ongoing disease that is free of apparent symptoms in order to avoid progression and (4) promoting health. Clinically managing ongoing disease that is manifested by experienced symptoms, discomfort or disability, therapeutic interventions and rehabilitation fall outside the review's focus. The reasoning for our narrowed scope is supported by conceptual and practical arguments. Conceptually, we follow Gordon's classification, that restricts the term prevention to primary and secondary levels. On the other hand, tertiary prevention follows after disease manifestation, which is in turn driven by different dynamics and often non-distinguishable from therapeutic activities.[39] Practically, keeping preventive and therapeutic interventions combined would enormously broaden up our review's scope and lead to an unmanageable amount of literature.

The term provider is defined as any professional that is responsible for offering health-related services, including health behavior and lifestyle changes (e.g. primary care physicians, primary care nurses, pharmacists, specialist physicians,

physiotherapists, psychologists, wellness providers, health and lifestyle coaches). This comprehensive definition aims to maintain a relatively broad scope and reduce the likelihood of missing potential valuable literature. The review will also incorporate studies where healthcare or wellness providers hold secondary roles, such as merely monitoring electronic PGHD, or providing input on the development of preventive digital PGHD-based tools, without direct interaction with patients. Even though the patient-provider interaction and provider involvement might be weak in such scenarios, they are crucial to fully understand the different approaches in using electronic PGHD for preventing disease and promoting health. Finally, table 2 outlines all PGHD dimensions targeted by our review, attaching those to corresponding questions and hypothetical examples.

Table 2	**Targeted PGHD Dimensions**
Dimension	**Corresponding Question & [hypothetical example]**
PGHD generation	How are PGHD created? [using a digital monitor to self-measure blood pressure]
PGHD collection	How are PGHD captured and stored [storing collected blood pressure values in an online patient portal]
PGHD communication & sharing	How are PGHD transferred? [using the patient portal to transfer blood pressure data to the general practitioner via secure e-mail services]
PGHD interpretation	How are PGHD reviewed and made sense of? [patient/provider views uploaded blood pressure measurements online over time to understand progress]
PGHD purposes	What is the intended purpose for collecting and using electronic PGHD? [self-regulation and personalized feedback]
PGHD utilization	(a) How are PGHD applied for achieving desired results? What is their actual use? [online portal sends provider-initiated

	feedback E-Mails, based on abnormal values] (b) Is their actual use in line with the intended purposes?
PGHD context	What are settings/environments of PGHD use? [electronic blood pressure measurements taken at home and at the work place]
PGHD impact	What are the effects or implications of PGHD? [control and course of blood pressure]

Protocol Structure

This protocol is structured and guided by Arksey and O'Malley's methodological framework for scoping studies, as well as Levac, Colquhoun and O'Brien's work on advancing that methodology.[40, 41] The following six sections are categorized according to the elements of that framework. Those include identifying the research question (Step 1), identifying relevant studies (Step 2), study selection (Step 3), charting the data (Step 4), collating, summarizing and reporting the results (Step 5) and stakeholder consultations (Step 6).[40, 41] Furthermore, this protocol follows the reporting guidelines of the PRISMA-P checklist for systematic review protocols.[42] Falling beyond the scope of a scoping review, the three PRISMA-P elements let aside are the risk of bias assessment, meta-biases and evidence strength (GRADE).[42]

Step 1: Identifying Research Question

Arksey and O'Malley describe the definition of an appropriate research question as a crucial initial step that defines and refines the chosen research strategy.[40] An iterative process of exchange, consultation and literature acquaintance led the development of the review's guiding questions. An expert has been consulted to provide further input and feedback on our predefined set of core and sub-questions. In line with our intention to comprehensively map and synthesize a potentially fast-growing and fragmented volume of literature on electronic PGHD, the review's primary, overarching research question is defined as: "*What is our knowledge status,*

retrieved from existing literature, on the generation, collection, communication, sharing, interpretation, utilization, context and impact of electronic PGHD for the facilitation of patient/consumer-centered preventive activities and health promotion?". Our question is focused on prevention or health promotion targets adults. A comparator is not defined, as our search will not be restricted to studies with controls.

Step 2: Identifying relevant studies

The identification of relevant literature will consist of several combined approaches, including electronic database searches and complementary activities, such as hand searches of selected online journals, relevant webpages, grey literature sources, reference list screening and expert consultations. Initially, we will systematically search 7 electronic databases, including Medline, CINAHL, PsycInfo, Scopus, Web of Science, EMBASE and IEEE Digital Library. Preliminary literature searches, consultation of thematically related reviews, input from the research team and the support of a specialized librarian led to pre-defined, preliminary search strategy, created on EMBASE and provided in supplementary file 1. Our strategy is purposively sensitive, entailing a variety of keywords related to PGHD, restricted to adult populations and research published in the last 15 years. Limiting our research to the last 15 years is based on our preliminary searches, that indicate an emergence and accumulation of relevant literature during the last decade. We purposively added another five years to ensure that we capture all valuable literature and trends. The final strategy will be refined in a consultation with the experienced librarian, who will run all searches. Retrieved documents will be imported into the electronic citation manager Mendeley.

In order to acquire the level of comprehensiveness required for a scoping review, we will also hand search key electronic journals, including JAMIA, JIMR, the International Journal of Digital Healthcare, Digital Health (SAGE) and the Journal of m-Health.[40] Grey literature, such as reports, policy briefs, conference abstracts and theses will be retrieved through rigorous searches of the following sources: Grey

Literature Report, Open Grey, Web of Science Conference Proceedings and Proquest Dissertations. Ensuring that no relevant publication is missed, we will run several web engine searches using Google, Google Scholar and Yahoo and screening the first ten result pages. Furthermore, we will screen thematically relevant webpages, such as the Office of the National Coordinator for Health Information Technology (ONC), the Healthcare Information and Management Systems Society (HIMSS), the Patient-Centered Outcomes Research Institute, the Research Triangle Institute International, the Agency for Healthcare Research and Quality (AHRQ) and Digital Health Canada. Our last research step consists of the manual reference list screening of all eligible studies as well as author consultations, requesting input on potentially missed or unpublished work.

Step 3: Study Selection

The study selection process will consist of two phases, independently conducted by two members of the research team. The first author of this protocol, having previous experience with literature reviews and an educational background in digital health interventions for disease prevention purposes, will take the first reviewer role. The second reviewer will be recruited based on substantial experience in planning and conducting literature reviews, an educational background in a health-related discipline and a good understanding of the proposed topic, preferably with previous work experience in a PGHD-related topic. Both will be responsible for independently completing the screening, selection and data extraction process, with the first reviewer having the added responsibility of data synthesis and final manuscript preparation. The first study selection phase includes the title and abstract screening of all identified documents. The second phase consists of full-text review of studies that have been classified as potentially eligible during phase one. During both phases, reviewers will assess study inclusion against a set of pre-defined eligibility criteria. To be eligible, studies have to have a clear focus on electronic PGHD, be linked to disease prevention and health promotion, address

adult populations and include some reference to patient and provider involvement. The absence of elements or indicators referring to prevention and health promotion (e.g. reduction of blood pressure) or a shallow exploration of patient or provider attitudes towards PGHD and PGHD-based tools, without being clearly defined within a prevention or health promotion context, will lead to exclusion. To ensure that the chosen eligibility criteria are sensitive and clear in capturing relevant documents, they will be pre-tested by both reviewers on a sample of studies that have been identified during preliminary searches. Maintaining a broad scope, our review will consider any type of primary research study designs as well as grey literature. Relevant systematic reviews will be considered as sources of potentially valuable primary research.

We will assess inter-rater agreement during both phases, using Cohen's k coefficient.[43] The coefficient, calculated after screening the first 50 titles and abstracts, will act as an indicator of whether both reviewers understand and apply the inclusion criteria in an equal, correct and coherent manner. Low agreement (<0.40) will be followed by a consultation of the two reviewers, and if needed, adjustment or rewording of the eligibility criteria. This process will be repeated for the next 50 titles and abstracts and until interrater agreement reaches substantial levels (>0.40). After the title and abstract screening is completed, the two reviewers will meet to compare their results. Consulting the inclusion and exclusion criteria, they will try to resolve conflicts and reach consensus on eligibility for full-text review. Studies that are unclear and do not allow for consensus will also enter full-text screening. During full-text review, which will be independently completed by the same two reviewers, interrater agreement will be calculated for the first 15 studies. After completion of full-text screening, reviewers will meet again to compare their results. All discordant articles will be reexamined and persisting disputes will be resolved through consultation with a third reviewer, selected among one of the senior members of the research team (MM, MP) and being responsible for the final decision on disputed papers. Both are members of Cochrane

Public Health Europe and have considerable thematic and methodological knowledge. To ensure the highest levels of process transparency and reproducibility, the entire process will be captured and visualized in a PRISMA flow chart, including the most common exclusion reasons, as well as the final number of included documents.[44]

Table 3 provides the selected exclusion criteria, carefully chosen to guide the identification of eligible studies, while counterbalancing the relatively high sensitivity that is inherent to the review's broad research question. Documents that fulfil one or more of the statements below will be excluded.

Table 3 Exclusion Criteria

1.	Does not address the generation, collection, communication, sharing, interpretation, utilization, context or impact of electronic PGHD (as outlined in Table 2)
2.	Lacks a focus on prevention and health promotion (e.g. exclusively addresses rehabilitation or therapeutic interventions)
3.	Addresses patient-generated information that is not personal health-related
4.	Does not describe, explore and analyse some form of patient and provider involvement
5.	Does not address or include adults
6.	Written in a language other than English or German

Step 4: Charting the data

Data extraction will be conducted independently by two reviewers, guided by a pre-defined, however flexible data extraction form. The preliminary form is developed by the research team and shown in table 4. It aims to ensure that all required information is captured practically, efficiently and accurately, minimizing the risk of missing information. Arksey and O'Malley's methodological framework suggests charting the data according to central research themes.[40] Thus, the chosen data-extraction elements have been developed in line with the review's objectives and corresponding research questions. Next to general information, we aim to retrieve data on PGHD types, patient and provider responsibilities, PGHD impacts on disease prevention and health promotion and equity.

The final form will be refined and validated through consultations with the entire research team, as well as expert feedback. As suggested by Levac et al. and Daudt et al., the form will be initially and independently tested by two reviewers on a random sample of five studies.[41, 45] This phase is described as as key to improving the quality and applicability of the data extraction chart.[45] It will be followed by consultation to ensure accuracy, consistency and that the captured information contributes to the study's research questions. Consultation might finally lead to form modifications that have to be reviewed and agreed upon by the entire research team.

After completion of the full data extraction process, both reviewers' final data-sets will be compared. Each article will have a unique identification number to enhance process efficiency and practicality. Inconsistencies and disagreements will be discussed, re-consulting the respective documents and if necessary, requesting support by a senior investigator of the team (MM, MP).

Table 4 Preliminary Data Charting Elements

Element & Sub-element	Associated Question
Publication Details	
Author & Affiliation	Who wrote the study/document?
Type	Is the document an empirical study or grey literature?
Year	What year was the study/document published?
Country/Region	Which country is the study/document focusing on?
Funding	Are the funding sources provided?
Conflict of Interest Declaration	Is a conflict of interest statement included?
General Details	
Methodological Design	What is the study/document design?
Aims	What are the study/document aims?
Population	Which is the target population of the study/document?
Addressed condition(s), risk factors(s), symptom(s), behavior(s) or outcome measure(s)	What is the health-related focus of the study/document?
Setting	What is the described setting?
Perspective (Promotion/Prevention)	Is the focus on prevention or health promotion?
Content	

Patient Roles and Activities ➢ PGHD generation ➢ PGHD transfer & use ➢ Context ➢ Barriers & Facilitators	What are the patient roles and required activities in generating, transferring and using electronic patient-generated health data (PGHD) for prevention/health promotion purposes?
PGHD Types ➢ Architecture ➢ Aims and Purposes	What types of PGHD are addressed? What PGHD-based tools are used? What are the intended PGHD purposes?
Provider Roles and Activities ➢ PGHD Integration ➢ PGHD use ➢ Purposes and Use ➢ Context ➢ Barriers & Facilitators	What are the provider roles and required activities in integrating and using electronic PGHD for prevention/health promotion purposes? Is the actual PGHD use in line with the indented purposes?
Interactivity ➢ Barriers & Facilitators	How do electronic PGHD affect or relate to patient-provider, as well as patient-technology interaction?
Impact on Prevention and Health Promotion-Related Outcomes	What is the impact of electronic PGHD use on any outcomes related to prevention and health promotion?
Equity Considerations	Does the study/document address, explore or refer to actual or potential equity-related implications of PGHD? (e.g. better results for disadvantaged social groups)
Other Important Results	Further important results?

Step 5: Collating, summarizing and reporting the results

As described by Arksey and O'Malley, a weighted data synthesis and aggregation of findings is not inherently essential to a scoping review, considering the missing assessment of evidence quality and robustness.[40] The chosen analytical approach will therefore be of narrative nature, guided by the adapted PGHD-flow framework (figure 1) and the review's objectives.[17] Despite its benefits, a quality assessment will not be performed as it does not align with our aim of scoping a potentially large and heterogeneous literature volume.

Initial synthesis will be of basic quantitative nature, summarizing the extent, scope and nature of existing literature. Publication types, years, geographic distribution, target populations, target conditions, risks and behaviors, as well as

existing methodologies will be synthesized descriptively, using ranges and counts, presented in tables. That step will provide an overview of existing evidence and research activity trends, as well as highlight potential research gaps.[40]

Further synthesis will remain narrative, but also consider quantitative primary data. Tables and figures will summarize key findings, structured around the review's objectives. The research team and experts will enrich data synthesis through regular input, ensuring validity and transparency. With exception of the risk of bias and evidence strength (GRADE) assessment, the reporting of our results will be guided by the PRISMA reporting guidelines.[46] The entire process, including screening (Step 3), data extraction (Step 4) and synthesis will be conducted with the Covidence Software and Excel. We are not planning any additional analyses.

Step 6: Consultation

Levac et al., pointed out that consultation, the sixth, transversal optional stage of the scoping studies framework, may enable stakeholder engagement and provide valuable input, beyond the information provided in the literature.[41] As already described throughout the protocol, expert consultation is central at all stages of this study. An external expert in the area of PGHD has been consulted twice during the development of this protocol, providing conceptual and content-related feedback and advice. During the review process, we will additionally establish regular consultation with one provider-partner and at least one patient-partner. Both stakeholders will be asked to provide feedback during data extraction, appraisal of preliminary results, data synthesis and interpretation. Finally, we aim to engage digital health experts within the team's own institution for additional advice. All involved experts and stakeholders will be acknowledged in the final publication.

Patient and Public Involvement

There was no patient or public involvement in the design of this protocol. Nonetheless, as outlined in the previous paragraph, at least one patient advisor will be consulted during the implementation stages of our review, asked to provide feedback on the clarity, applicability and value of the review's findings and interpretations. Any involved patient-partner will receive our preliminary and final results electronically and during consultations.

ETHICS AND DISSEMINATION

The described review constitutes the first step of a larger research project on digital solutions for disease prevention and health promotion. Its results ultimately fulfill the function of establishing a comprehensive conceptual knowledge of electronic PGHD and will be used to inform prospective research steps. Initiation of screening and data collection is planned for February 2018. Findings will be disseminated at relevant conferences and symposia. Results will be published and additionally shared with our provider and patient-partners and their networks, as well as local and national organizations operating in the field of digital health. As our methodology is based on the review of publicly available information, ethical approval is not required. Any amendments to this protocol will be documented precisely and listed in the final review publication.

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the entire process and edited the manuscript. Milo Puhan contributed to the conceptualization of the study, supervised the entire process and edited the manuscript. Frederic Ehrler provided regular input and edited the manuscript. All authors provided final approval of the final protocol version.

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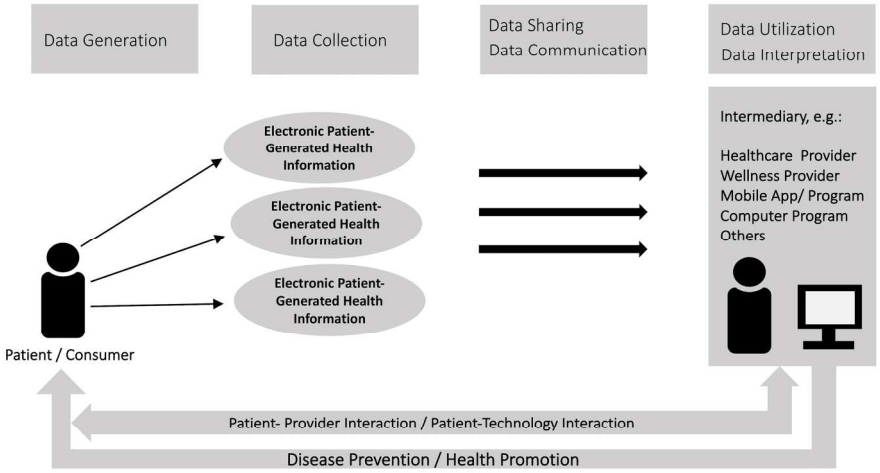
Figure Legends

Figure 1: Adapted Framework for Patient-Generated Health Data (PGHD) Flow and Context for Prevention and Health Promotion.[17]. The Framework visualizes the flow of PGHD from the patient/consumer (generation & collection stages), passing through intermediaries (communication, sharing & interpretation stages) and back to the patient in form of prevention, health promotion and interaction (utilization & impact stages).



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190x107mm (300 x 300 DPI)

Supplementary File 1: Preliminary Search Strategy, piloted on EMBASE

#1	((patient NEXT/1 (reported OR shared) NEAR/3 (data OR information)):ti,ab) OR (((consumer OR people OR user OR person*) NEXT/1 reported NEAR/6 (health OR medical OR clinical) NEXT/1 (information OR data)):ti,ab) OR ((connected NEXT/1 (health OR medicine)):ti,ab)
#2	((patient NEXT/3 portal):ti,ab) OR (((electronic OR digital OR online OR web* OR internet) NEXT/3 'health diary'):ti,ab)
#3	'electronic patient record'/exp OR 'electronic medical record'/exp OR 'electronic health record'/de OR 'telemedicine'/exp OR (((personal OR user OR consumer OR electronic OR online OR digital OR web OR internet OR computer) NEAR/1 (medical OR health OR clinical) NEXT/1 record):ti,ab) OR ((patient* NEXT/3 record):ti,ab
#4	((patient OR consumer OR people OR user OR person* OR self*) NEXT/1 (generated OR reported OR shared)):ti,ab
#5	self:ti,ab OR oneself:ti,ab OR himself:ti,ab OR herself:ti,ab OR personal*:ti OR connected:ti,ab OR ((personal* NEXT/3 (health* OR medicine* OR care OR manag* OR monitor*)):ti,ab)
#6	#4 OR #5
#7	#3 AND #6
#8	#1 OE #2 OR #7
#9	promot*:ti OR prevent*:ti OR improve*:ti OR (((health OR patient) NEAR/3 (educat* OR communicat* OR advocacy OR literacy OR behaviour OR behavior OR status)):ti) OR (((disease OR health OR personalized) NEXT/3 manag*):ti) OR ((self NEXT/1 (manag* OR monitor*)):ti)
#10	#8 AND #9
#11	'health promotion'/exp OR 'health literacy'/exp OR 'health education'/exp OR 'disease management'/exp OR 'health behavior'/exp OR 'health status'/exp OR ((health NEAR/1 (promot* OR prevent* OR educat* OR communicat* OR advocacy OR literacy OR behaviour OR status)):ti,ab) OR ((disease NEAR/1 manag*):ti,ab) OR (((disease OR medicine) NEAR/3 prevent*):ti,ab) OR ((self NEXT/1 (manag* OR monitor*)):ab)
#12	'devices'/exp OR 'internet'/exp OR 'information processing'/exp OR (((electronic* OR mobile OR smart) NEXT/3 (tool* OR watch* OR device* OR gadget* OR bracelet* OR pager* OR monitor*)):ti,ab) OR (((mobile OR cell OR smart) NEXT/3 phone):ti,ab) OR tablet*:ti,ab OR iphone*:ti,ab OR ipad*:ti,ab OR smartphone*:ti,ab OR wearable*:ti,ab OR app:ti,ab OR apps:ti,ab OR application*:ti,ab OR ((technol* NEAR/3 (consumer OR patient OR user)):ti,ab)
#13	innovat*:ti,ab
#14	#12 OR #13
#15	#8 AND #11 AND #14
#16	#8 AND #11 AND #12
#17	#10 OR #15

#18	((patient NEXT/1 generated NEAR/3 (data OR information)):ti,ab) OR (((consumer OR people OR user OR person*) NEXT/1 generated NEAR/6 (health OR medical OR clinical) NEXT/1 (information OR data)):ti,ab) OR ((connected NEXT/1 (health OR medicine)):ti,ab)
#19	(connected NEXT/1 (health* OR medicine OR treat* OR monitor* OR care*)):ti,ab
#20	#17 OR #18 OR #19
#21	'electronic patient record'/exp OR 'electronic medical record'/exp OR 'electronic health record'/de OR 'telehealth'/exp OR 'medical informatics'/exp OR (((personal OR user OR consumer OR electronic OR online OR digital OR web OR internet OR computer) NEAR/1 (medical OR health OR clinical) NEXT/1 record):ti,ab) OR ((patient* NEXT/3 record):ti,ab) OR (((electronic OR digital OR mobile OR tele) NEXT/1 (health OR care OR monitoring)):ti,ab) OR 'e health':ti,ab OR 'm health':ti,ab OR 'e care':ti,ab OR 'm care':ti,ab OR 'e monitoring':ti,ab OR 'm monitoring':ti,ab OR 'internet of things':ti,ab OR telemedicine:ti,ab OR ((health NEXT/1 (it OR 'information technology')):ti,ab)
#22	#6 AND #21
#23	#1 OR #2 OR #22
#24	#9 AND #23
#25	#11 AND #14 AND #23
#26	#18 OR #19 OR #24 OR #25
	Date: 12.12.2017 Filters: Adult, Human, English & German, 2003 – to present

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Where to find
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	p. 1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	NA
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	NA
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	p. 1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	p. 21
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NA p. 21
Support:			
Sources	5a	Indicate sources of financial or other support for the review	p. 21
Sponsor	5b	Provide name for the review funder and/or sponsor	NA
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	NA
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	p. 6-7
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	p. 12-13
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	p. 14-17
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	p. 14-15
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be	Supplementary

		repeated	file 1 & p. 13
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	p. 13, 19-20
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	p. 14-17
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	P. 17-19
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	P. 18-19
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	P. 18-19
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	NA – reason given on p. 13
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	p. 19
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	p. 19
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	p. 20
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	p. 19-20
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	NA – reason given on p. 13
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	NA – reason given on p. 13

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.